"Delay in presentation to the hospital and factors affecting it among the breast cancer patients"

Dissertation

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ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BHOPAL

In partial fulfillment of the requirement for the degree of M.Sc. in Medical Surgical Nursing (Oncology Nursing)

by

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July 2024

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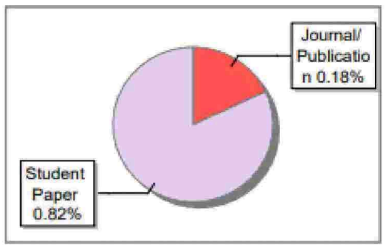

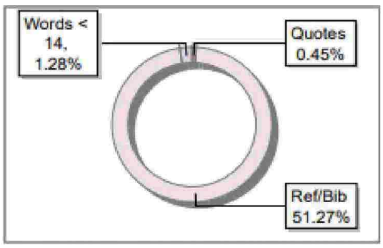

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AIIMS, Bhopal Institutional Human Ethics Committee- Student Research (IHEC-SR) in its 7th meeting held on 22nd February 2023 discussed your proposal titled **"Delay in presentation to the hospital and factors affecting it among the breast cancer patients"** and evaluated it for suitability for your dissertation as required for fulfilment of MSc (Nursing).

Following members attended the meeting:

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The decision of the committee is as follows:

The AIIMS, Bhopal IHEC-SR approves your research protocol. All research related activities must begin only after the date of this approval. The validity of this approval is till two years from the date of issuance. Please submit a closure report / renewal request before expiration of the validity for this approval.

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The big talent is persistence." – Octavia E. Butler

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Ms. Kajal Nehra

ABSTRACT

ABSTRACT

Introduction:

In India, there is a significant prevalence of breast cancer cases and a relatively high mortality rate, largely attributed to patients seeking medical attention at an advanced stage of the disease. Unfortunately, delayed presentations are linked to less favourable prognoses. Numerous underlying problems contribute to this growing burden. The current research aims to address the extent of delay in presentation and the factors that contribute to delayed presentation among breast cancer patients.

Methods:

A detailed retrospective analysis of 138 primary breast cancer patients attending oncology OPD at All India Institute of Sciences (AIIMS), Bhopal over a period of approximately 2 months (September 2023 to November 2023) was done. A self-structured questionnaire consisting of socio-clinical variables, duration of presentation delay and various factors affecting delayed presentation was used to collect the data. Data was collected through face-to-face interview. Factors affecting delayed presentation were identified using multiple logistic regression analysis.

Results:

There were 43.5% respondents with the age ranged between 40-50 years. The majority of respondents did not have a family history of breast cancer. The median delay in presentation to the hospital was 2 months, with a range spanning from 15 days to 3 years. Women having breast lump as initial breast symptom tend to present late (>3 months) to the

hospital($p = 0.037$) and if the breast lump was smaller, they are more likely to delay seeking medical attention compared to those with larger breast lump ($p = 0.012$).

Conclusion:

Breast cancer is a prevalent cancer. The significant worry lies in delays in seeking medical attention and the tendency for individuals to present at advanced stages. The results of the study suggest that considerable number of patients experienced a small breast lump as a significant reason for the presentation delay. Therefore, better screening strategy related services for early identification can be provided and future awareness campaigns should highlight that breast lumps are highly associated with breast cancer, which may help in reducing percentage of delayed presentation and further increase quality of life of the patients.

Keywords:

delayed presentation, factors, determinants, breast cancer, duration of symptoms

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6.	Evaluation criteria for validation of the tool
7.	Content validity certificate
8.	Translation certificate (Hindi)
9.	Translation certificate (English)
10.	Letter seeking permission to conduct the study
11.	Participant Information sheet (English)
12.	Participant Information sheet (Hindi)
13.	Informed Consent form
14.	Master data sheet

LIST OF ABBREVIATIONS

S.NO	ABBREVIATIONS	EXPANSION
1.	AIIMS	All India Institute of Medical Sciences
2.	CVI	Content Validity Index
3.	f	Frequency
4.	HOD	Head of Department
5.	IHEC-SR	Institutional Human Ethics Committee- Student Research
6.	K-S Test	Kolmogorov-Smirnov Test
7.	LOP	Letter of Permission
8.	M.Sc.	Masters of Sciences
9.	N	Sample Size
10.	OR	Odds Ratio
11.	OPD	Outpatient Department
12.	PG	Post Graduate
13.	SCVI	Scale Content Validity Index

LIST OF SYMBOLS

S.NO	SYMBOLS	EXPANSION
1.	%	Percentage
2.	>	More than
3.	<	Less than
4.	≥	Equal to or more than
5.	H0	Null Hypotheses
6.	H1	Research Hypotheses
7.	p	Level of significance
8.	d	precision
9.	&	And
10.	=	Equal to

CHAPTER I

INTRODUCTION

CHAPTER – I

INTRODUCTION

Background of the study

In 2020, global cancer incidence reached an estimated 19.3 million cases, with India ranking third globally, following China and the United States of America, according to the Global Cancer Observatory (GLOBOCAN) estimates.[1,2] In 2020, breast cancer stood as the most prevalent cancer worldwide. During that year, a staggering 2.3 million women received a diagnosis of breast cancer, and tragically, there were 6,85,000 breast cancer-related fatalities reported across the globe.[1] A remarkable 7.8 million women were still living, having been diagnosed with breast cancer within the preceding five years..[1] According to the data from 2020, in India, breast cancer constituted 13.5% of all reported new cancer cases, total 1,78,361 new cases. Sadly, it was responsible for 10.6% of all cancer-related fatalities, claiming 90,408 lives.[2] The cumulative risk of developing breast cancer in India was calculated to be 2.81.[2] The escalating prevalence of breast cancer, both on a global scale and specifically within India, has emerged as a profound cause for concern.[1] Not only is breast cancer the most prevalent site-specific cancer, but it also stands as the primary cause of cancer-related mortality among women.[1] In India, the significant total number of breast cancer cases and the high net mortality rate can be attributed to the limited availability of extensive screening programs and a lack of widespread educational initiatives on the disease.[1,4]

It is unsurprising that a majority of breast cancer patients in India receive treatment at the locally advanced and metastatic stages of the disease.[7] The continually rising prevalence of breast cancer is merely the visible part of a larger issue.[11] Numerous underlying problems contribute to this growing burden. In India, close to 60% of breast cancer cases

are identified at stages III or IV of the disease.[11] The initial presentation of breast cancer, typically in the form of a lump, is often not accompanied by pain.[11,12] This characteristic contributes to a delay in seeking treatment, affecting 50% to 70% of cases in rural areas.[11,12] A delayed presentation at a later stage is associated with a less favourable prognosis.[9] It was observed that the period between women self-detecting a breast lump and their hospital presentation ranged from 2 days to 6 years.[9] The median time lapse was 6 months, indicating that more than half of the women took over 6 months to seek medical advice for the lump.[9]

The majority of patients seek healthcare only when they have a noticeable, sizable mass or when secondary changes like local skin or chest wall alterations become visible.[11] Women often disregard minor symptoms and delay seeking medical attention due to their household responsibilities.[11] Other contributing factors to late presentation include a lack of awareness about the disease, particularly in rural areas.[11] Consequently, fewer women engage in breast self -examinations, opting for periodic healthcare worker assessments or mammography for breast cancer screening, even though it is available for free at selected government hospitals.[11] For those willing to pay for it, mammography is accessible in private healthcare facilities. Unfortunately, this lack of awareness regarding the risk factors and early detection methods of breast cancer is prevalent, affecting even 49% of healthcare workers.[11] Many prevalent myths and widespread ignorance within Indian society contribute to an unwarranted fear of breast cancer.[5,6] This often deters women from seeking timely medical care for various reasons, including illiteracy, limited awareness, and financial constraints.[5,6] Women with lower financial means were more prone to encountering delays in seeking medical attention.[17] The delay in presentation is primarily ascribed to a multitude of barriers prevalent in the Asian region.[9] These barriers encompass structural challenges, such as inadequate healthcare infrastructure, long

distances to healthcare facilities, and difficulties in taking time off work.[9] Additionally, organizational hurdles include navigating the intricate healthcare system and interactions with medical personnel.[9] Psychological and socio-cultural impediments further contribute to delayed presentation and encompass factors like low health motivation, denial of personal risk, fatalistic beliefs, scepticism towards cancer treatments, and the fear of becoming a burden to family members.[9] Age, educational background, occupation, place of residence, consultation with traditional healers, the presence of an armpit lump, and concurrent medical conditions emerge as significant factors contributing to delayed presentation.[18] Women who refrained from seeking the services of a traditional healer were 62% less likely to experience delays compared to those who did consult a traditional healer.[18] Breast cancer patients without an armpit lump were roughly 9 times more inclined to experience delays in comparison to their counterparts.[18] Women with breast cancer cited three primary reasons for their delayed arrival at health facilities: underestimating the seriousness of the disease, lacking sufficient awareness about the symptoms, and seeking assistance from traditional healers.[18] The breast symptoms were not causing any pain or discomfort was the most common reason for presentation delay of ≥3 month.[19]

Significant delays substantially raised the likelihood of presenting with an advanced stage of the disease, which in turn was linked to a heightened probability of mortality.[19] A more extended delay in presentation showed a significant association with decreased survival.[16]

Significance and need of the study

In India, there is a significant prevalence of breast cancer cases and a relatively high mortality rate, largely attributed to patients seeking medical attention at an advanced stage of the disease.[8] To address this growing burden of breast cancer-related mortality, it is

imperative to prioritize early detection strategies and promote greater utilization of systemic therapy.[2] Timely detection and treatment play a crucial role in managing breast cancer effectively. [2] Early detection hinges on the prompt presentation of individuals to healthcare facilities. Therefore, it is essential to identify the factors that contribute to delays in seeking medical attention at hospitals.

Minimizing treatment delay is paramount for improving the outcomes in breast cancer. Any delay in either the initial presentation or subsequent treatment can lead to a notable deterioration in the progression of the disease, underscoring the urgency of timely medical attention. Early detection of breast cancer is instrumental in reducing the necessity for intensive treatment, thereby resulting in lower healthcare costs, diminished side effects, and an overall enhancement in the quality of life for patients.

In contrast to numerous studies conducted in foreign countries that have assessed the delay in breast cancer presentation and the factors influencing delayed presentation, there is a noticeable dearth of research on this topic in India. Therefore, the current research aims to address this gap by investigating the extent of delay in presentation and the factors that contribute to delayed presentation among breast cancer patients in the Indian context. Numerous factors contribute to women's propensity to delay seeking medical attention at the early stages of breast cancer when treatment holds the highest prospects for success. This study aims to establish a foundational dataset, serving as a basis for designing future interventions to mitigate delayed presentation and therefore, diagnosis and treatment of breast cancer.

Research problem

A study to assess the delay in presentation to the hospital and factors affecting it among the breast cancer patients taking treatment at a tertiary care hospital, Bhopal.

Research questions

1. How much is the time lag since first recognition of breast cancer symptoms and presentation to the hospital among breast cancer patients?
2. What are the various factors affecting delayed presentation to the hospital among breast cancer patients?
3. Is there any association of sociodemographic variables and clinical variables with delay in presentation to the hospital among Breast Cancer patients?

Aim of the study

The study aimed to assess the time lag since first recognition of breast cancer symptoms and presentation to the hospital and factors affecting delayed presentation to the hospital among breast cancer patients .

Objectives of the study

1. To assess the time lag since initial recognition of breast cancer symptoms and presentation to the hospital among breast cancer patients.
2. To identify various factors affecting delayed presentation to the hospital among breast cancer patients .
3. To find out association between socio-demographic variables and clinical variables with delay in presentation to the hospital among breast cancer patients.

Hypotheses

$H0_1$: There is no significant association between delay in presentation to the hospital and factors affecting delayed presentation to the hospital among breast cancer patients.

$H0_2$: There is no significant association between Socio-demographic variables and clinical variables and delay in presentation to the hospital among breast cancer patients.

H1 : There is a significant association between delay in presentation to the hospital and factors affecting delayed presentation to the hospital among breast cancer patients.

H2 : There is a significant association between Socio-demographic variables and clinical variables and delay in presentation to the hospital among breast cancer patients.

Assumptions

1) Delay in presentation to the hospital may be there among breast cancer patients.
2) Various physical, psychological, socio-cultural and knowledge factors may influence delayed presentation to the hospital among breast cancer patients
3) Time of presentation to the hospital and factors affecting delayed presentation among breast cancer patients may vary person to person.

Operational definition

1. Delay in presentation : Late seeking medical attention after observing a breast cancer symptom. In this study , it refers to time lag of more than 2 weeks since initial recognition of breast cancer symptoms and first medical interaction among breast cancer patients and it was measured using self-structured questionnaire.
2. Factors affecting delayed presentation : In this study the various factors which are responsible for late seeking medical attention by breast cancer patients and it include:
    1) Physical factors (e.g. Distance to the health-care facility, busy in work etc.)

2) Knowledge factor (e.g. Didn't know about breast cancer etc.)
3) Psychological factor (e.g. Fear, embarrassment etc.)
4) Socio-cultural factor (e.g. Financial or religious factors etc.)

and it was assessed using self- structured questionnaire.

Delimitations

This study is delimited to Oncology Department of All India Institute of Medical Sciences (AIIMS) Bhopal.

Conceptual Framework

Leventhal's model / Common- Sense model of self-Regulation[10]

The Common-Sense Model of Self-Regulation, commonly known as the CSM, is a widely accepted theoretical framework that delineates the different stages through which individuals comprehend a health threat. These stages include becoming aware of the threat, managing emotional responses to it, forming perceptions about the threat and potential treatment options, devising action plans to address the threat, and incorporating ongoing feedback to assess the effectiveness of the action plan in light of the threat's progression.[10]

The authors introduced a hierarchically structured adaptive system consisting of three key constructs:

(i) The representation of illness experiences, which can impact

(ii) The formulation of action plans and coping responses, as well as their execution, and

(iii) The appraisal process, involving the assessment of the effectiveness or shortcomings of coping strategies.

A unique aspect of Leventhal's proposition was the simultaneous and parallel cognitive processing of how individuals manage their reactions to both the 'perceived health threat' (involving questions like 'What is the nature of the health threat, and what practical actions can I take?') and the "emotional control" (entailing considerations such as How do I emotionally respond to it, and what can I do to enhance my emotional well-being in light of it?). [11]

Leventhal and his colleagues elucidated five distinct components, which are:

1. **Identify:** This involves considering not only the labels associated with the condition but also the symptoms commonly associated with it. It can be argued that individuals often seek a label for their symptoms, possibly to validate their experiences. However, once they have such a label, they might be more inclined to interpret various symptoms as evidence confirming that label. In the current study, we examine whether participants can recognize their symptoms as potential indicators of breast cancer.

2. **Timeline:** The timeline component involves assessing the participant's perception of the ailment's duration, specifically whether it is perceived as an acute issue or likely to become chronic. This plays a critical role in the participant's decision-making process regarding seeking immediate medical assistance or waiting for symptoms to resolve. In the present study, participants either waited for symptoms to alleviate or perhaps did not initially consider the symptoms as a serious concern, among other potential reactions.

3. **Consequences:** It involves how individuals personally perceive the potential outcomes of their condition and the subsequent physical and social impacts they anticipate. This study evaluates whether the patient was embarrassed to talk about her condition or had fear what others will think etc.

4. **Cause:** The individual's perception of the condition's causation, which may or may not align with strictly biomedical explanations, is influenced by personal experiences as well as the perspectives and discussions of significant individuals in their life. Age, use of Oral Contraceptive Pills or family history of breast cancer can be perceived as a cause.

5. **Cure/ Control:** This component explores the extent to which the individual perceives their agency in achieving a potential cure or maintaining control over the condition. It encompasses whether the patient communicates their breast change symptoms to healthcare professionals and whether they have pursued any other measures, such as alternative treatments , to manage pain or cope up with the symptoms.

These 5 factors that comprise the illness threat are also subject to emotional responses to health threats, which, in turn, impact the 3 primary stages of the framework:

Interpretation, coping and appraisal

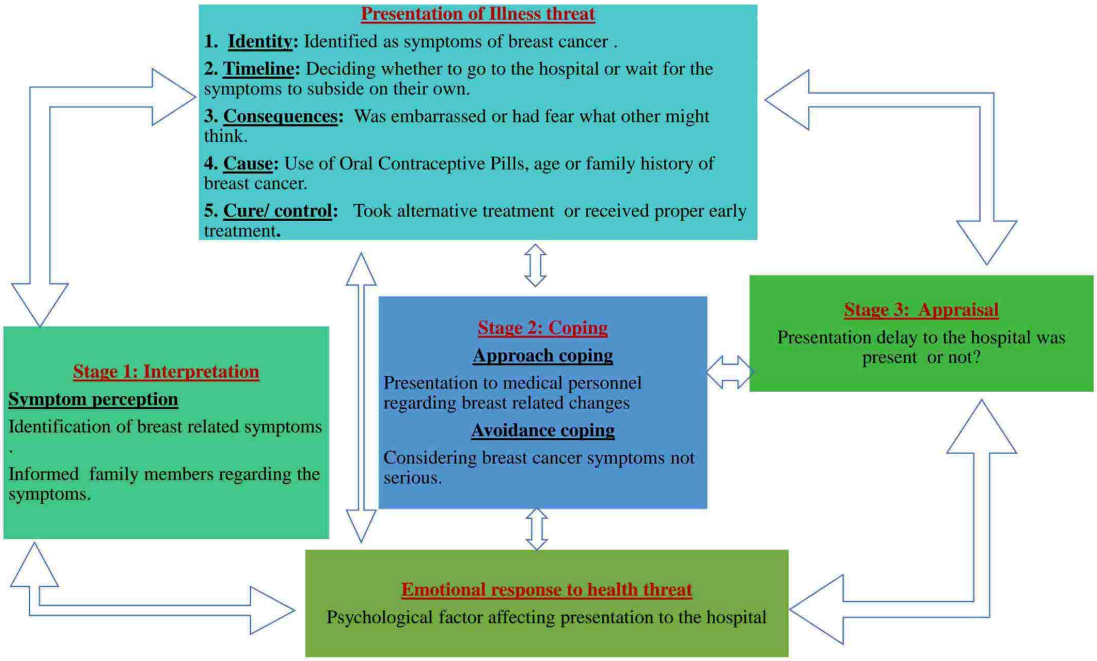
Presentation of Illness threat
1. Identity: Identified as symptoms of breast cancer .
2. Timeline: Deciding whether to go to the hospital or wait for the symptoms to subside on their own.
3. Consequences: Was embarrassed or had fear what other might think.
4. Cause: Use of Oral Contraceptive Pills, age or family history of breast cancer.
5. Cure/ control: Took alternative treatment or received proper early treatment.
Stage 1: Interpretation
Symptom perception
Identification of breast related symptoms .
Informed family members regarding the symptoms.
Stage 2: Coping
Approach coping
Presentation to medical personnel regarding breast related changes
Avoidance coping
Considering breast cancer symptoms not serious.
Stage 3: Appraisal
Presentation delay to the hospital was present or not?
Emotional response to health threat
Psychological factor affecting presentation to the hospital

Figure 1 : Conceptual framework based on Leventhal's self-regulatory model

CHAPTER II

REVIEW OF LITERATURE

CHAPTER – 2

REVIEW OF LITERATURE

This chapter focuses on the review of research studies pertinent to the current investigation.

An extensive literature search has been done in various search databases like PubMed, Google Scholar, Scopus, using the keywords delayed presentation, factors, breast cancer. In the present study review of literature is presented under the following heading:

1. Studies related to burden of breast cancer.
2. Studies related to delay in presentation and factors affecting delayed presentation to the hospital among breast cancer patient.

1. Studies related to burden of breast cancer.

According to WHO report in 12 July 2023, as of 2020, breast cancer remained a significant global health concern, with 2.3 million women receiving diagnoses and 685,000 women succumbing to the disease. By the close of 2020, a substantial 7.8 million women were living with a recent diagnosis of breast cancer within the previous five years, solidifying its status as the most prevalent cancer worldwide.[1]

As per the report relying on the GLOBOCAN database, breast cancer stands out as the most prevalent cancer globally and maintains a substantial influence on the overall

number of cancer-related fatalities. There is a crucial need for global initiatives to address its increasing burden, particularly in transitioning countries experiencing a rapid rise in incidence and persistently high mortality rates. In India, there were 67,109 new cases of breast cancer reported in 2020 for individuals under the age of 50, while there were 111,252 new cases for those aged 50 and above. Additionally, there were 22,603 deaths due to breast cancer under the age of 50 and 67,805 deaths among individuals aged 50 or older.[24]

According to the report given by National Cancer Registry Programme, India, Projected incidence of breast cancer in India in 2020 was 5,377 in male and 205,424 in females. There is significant increase in the incidence rate of breast cancer across Bhopal from 1988 to 2015.[37]

2. Studies related to delay in presentation and factors affecting presentation delay to the hospital among breast cancer patients.

A retrospective study was conducted between 2010 - 2011 among 120 primary breast cancer patients visiting tertiary care hospital in India with aim to study the time lag since detection of lump by woman and presentation to the hospital and factor affecting them. Study revealed a median delay in the presentation to the hospital among breast cancer patients was 6 months, and presentation delay to the hospital varies from 2 days to 6 years. After detecting a breast lump, 28.24% of patients presented to the hospital within 2 to 5 months, 45.88% presented between 6 to 12 months, and 5.88% presented after 12 months. Study reported that demographic involving lower socio-economic status, older age and female living in rural areas are more prone to present late to the hospital after self-discovering a breast lump.[9]

A mixed method study was conducted among 300 breast cancer patients at AIIMS Rishikesh, India to understand the factors that contribute to the delay in breast cancer patients. The study finds the median delay in hospital presentation was 5 months, with an interquartile range spanning from 4 to 8 months. The primary cause of presentation delay, as reported by 55.0% of participants, was the presence of an asymptomatic breast lump. Subsequently, 13.7% of females acknowledged using Ayurvedic medicines, while 11.1% opted for homoeopathic remedies. Awareness about breast cancer symptoms was found in only 39% of women, and a noteworthy 80% of patients lacked awareness regarding the causes of breast cancer.[22]

A mixed- method study was conducted from 2015 to 2020, using a structured questionnaire, data of 303 women diagnosed with advanced breast cancer was collected to determine the extent of help seeking delay among Malaysian breast cancer patients who present at late stage. The study concluded that the median delay of help seeking was 65 days, with almost half of the women delayed help seeking by > 3 months and 18% of the patient reported after one year of delay. In the present study lack of knowledge was the most common barrier in help seeking followed by emotional barriers and optimism.[32]

A cross sectional survey was conducted among 330 women attending radiotherapy department of a tertiary care centre in South India to estimate the delay in seeking treatment among women with carcinoma of breast and determine the factors associated with delay. The study concluded that 33.5 % patient had presentation or patient related tile with three months cut-off. In multivariate analysis knowledge regarding breast cancer(OR=3.96) and appraisal time(OR = 2.01) was statistically significant.[26]

A retrospective observational study was conducted between 2018 - 2022 among 150 Indonesian female breast patients. The study revealed a median delay in hospital presentation of 2 months. Out of the respondents, 56.7% sought consultation with a medical professional within 3 months of detecting their symptoms, whereas 43.3% postponed their consultation by ≥3 months. The study indicates that the most common reason (41.5%) for delayed consultation was the perception that the initial symptom was not bothersome and not indicative of a serious problem. This was followed by the belief that the symptoms were not related to cancer or a serious medical condition (27.7%), fear of undergoing surgery (26.2%), and being too busy (13.9%).[19]

A cross-sectional study conducted in 2020 aimed to identify factors associated with delayed presentation among women experiencing breast symptoms. Employing a cross-sectional approach, the study revealed a median delay of 4 months, ranging from 2 weeks to 24 months. Notably, a higher frequency of delay was observed within the 3 to 6 months timeframe. Regression analysis demonstrated a significant association between delayed presentation and the perception of symptoms as not being serious($p = 0.030$). [33]

A cross-sectional study conducted in 2020 involving 204 women diagnosed with breast cancer in North East Ethiopia. The study aimed to determine the prevalence of patient delay at presentation among breast cancer patients and identify associated factors. The findings revealed a median delay of 4 months, with 50.5% of women experiencing delays exceeding 3 months. The most prevalent reason for delayed hospital presentation, accounting for 90.7%, was the participants' lack of consideration of the disease as a serious health concern. Additionally, 55.4% of women lacked awareness about breast

cancer symptoms, and 33.3% sought the services of traditional healers. Demographic factors, such as age over 40, illiteracy, unemployment, and rural residence, were identified as significant contributors to the delay in seeking medical attention at a health facility.[21]

A mixed method study was conducted in 2019 with an aim to estimate the overall delay in diagnosis and treatment in breast cancer and associated factors. Total 269 breast cancer patient were analysed and found the presentation median delay of 35 days with range of 10 to 112 days. Reasons for presentation delay were found to be misconception about the disease, perceived stigma, fear and denial of cancer, attribution of symptom to trivial conditions, family responsibilities and embarrassment of breast examination by a male doctor. [28]

A cross-sectional study conducted in 2017, with the objective to identify the factors affecting presentation delay to the hospital among breast cancer female patients in the occupied Palestinian territory, which disclosed a median waiting time of 14 days preceding the initiation of seeking medical assistance, along with an average waiting period of 74.6 days. The study also indicates that 49% of women did not perceive the symptoms as serious, 34% harboured a fear of receiving a diagnosis, and 29% did not experience pain, consequently leading to a delayed initiation of seeking medical attention.[20]

A cross-sectional study conducted in Brazil between 2012 and 2014, involving 444 breast cancer patients, utilizing a structured questionnaire. Among the participants, the mean age at diagnosis was 52.3 years. The study revealed a median delay of 39 days, with 34% of participants experiencing delays of up to 90 days. The study identifies that a primary

factor contributing to the delay in hospital presentation was a lower educational level and the absence of mammography or breast ultrasound examinations within the two-year period.[23]

A Retrospective study was conducted in 2006 with an objective to analyse the distribution of Socio-economic and demographic factors among breast cancer patients. Total 522 breast cancer patients were analysed and in multivariate analysis , it was observed that increased risk for late-stage reporting were observed unmarried, widowed/divorced women and women with lower education.[27]

An observational study was conducted between 2017 to 2018 with an aim to identify patient perceived barriers to breast cancer management in male and female breast cancer patients. Total 435 participants were analysed self-structured questionnaire. It was observed that 41.1% participants delayed presentation to the hospital with a median delay of 4 month. The results indicate that 53.9% of patients believed that symptoms would resolve on their own, while 18% reported delayed presentation due to social stigma.[30]

Gaps and Trends in Literature

Fifteen studies published between 2006 and 2023 were reviewed and organized according to their relevance to the study topic and the year of publication. This review process aided the researcher in comprehending previous work and in developing the research methodology and data collection tools. Although numerous studies have investigated presentation delay among breast cancer patients, not all relevant factors have been considered consistently across these studies. Therefore, the researcher aims to

conduct a study in Bhopal to examine various factors associated with presentation delay among breast cancer patients.

CHAPTER III

MATERIALS & METHODS

CHAPTER – 3

MATERIALS AND METHODS

Research methodology is a structured approach for methodically addressing research problem, serving as the framework to investigate and understand scientific research processes.[13]

This chapter provides a brief description of the method adopted by the researcher to conduct this study. It includes research approach, research design, setting of the study, sample and sampling technique etc.

RESEARCH APPROACH

A research approach encompasses a strategic blueprint used by the researcher to establish the most effective techniques for gathering, analyzing, and interpreting data. It serves as the foundational framework that guides the researcher in producing precise and comprehensible information.[15]

In this study quantitative approach was adopted to achieve the objectives of the study.

RESEARCH DESIGN

The research design adopted for this study is descriptive research design as it was found effective to assess delay in presentation to the hospital and factors affecting delayed presentation among breast cancer patients.

RESEARCH VARIABLES

Research variables: Delay in presentation to the hospital, factors affecting delayed presentation to the hospital.

Sociodemographic variables: Age, level of education, occupation, marital status, residence, number of children, religion, history of oral contraceptive pills use, socio-economic status using Kuppuswamy scale.

Clinical variables: First observed change in breast, family history of breast cancer, breast self- examination, comorbid disease.

Research setting

This study was conducted in Oncology Out Patient Department (OPD) of a tertiary care hospital; All India Institute of Medical Sciences (AIIMS) Bhopal. AIIMS Bhopal is an Institute of National Importance (INIs) situated in Bhopal district of Madhya Pradesh. AIIMS Bhopal is a tertiary care hospital having total bed count of 1108 beds. There is a well-functioning Oncology Out Patient Department (OPD) which is selected as the setting for present study since breast cancer female patients attend the OPD for follow-up, chemotherapy etc. in AIIMS Bhopal.

Population

Target population = Females who were diagnosed with breast Cancer.

Accessible population= Female Breast Cancer patients who were taking treatment at AIIMS Bhopal.

Sample: Breast cancer patients who had taken treatment during the course of the study at AIIMS, Bhopal and met the inclusion and exclusion criteria were the sample of this study.

Sampling criteria

- **Inclusion criteria**
  - Breast Cancer female patients of age between 18 – 60 years.
  - Breast Cancer patients willing to participate in the research study.

- **Exclusion criteria**
  - Breast Cancer patients having <2 weeks of time lag between initial recognition of breast cancer symptom and first medical interaction.
  - Breast Cancer patients not able to understand both Hindi and English.
  - Patients diagnosed with cognitive impairment , psychological problem and who are unable to give responses.
  - Patients with recurrence of breast cancer and patient with any other cancer that metastasize to the breast.
- **Sample size** = Based on pilot study results, prevalence of 6 month delayed presentation among breast cancer patients was 6.6% , sample size was estimated by using formula:

$$N = [Z_{(1-\alpha/2)}]^2 Pq/d^2$$

N= 94 (Enrolled, N = 138)

where,

P = Expected proportion of event of interest = 0.066

q = 1- P = 0.934

$Z(1-\alpha/2)$ = Normal distribution table value i.e. 1.96

d = precision = 0.05

Calculated sample size was 94, whereas total number of participants enrolled for the study are 138.

- **Sampling technique:** In this study non probability convenient sampling technique was used as it is more practical and suitable.

Data collection tool and instruments

- **Development and description of tool**

The cornerstone of any research lies in the acquisition of appropriate information. Data collection represents the systematic process through which researchers gather relevant data from various sources, enabling them to address research questions, test hypotheses, and assess the ultimate outcomes.[14] A tool is an instrument used to collect the desired information.[15] The following steps were adopted in the development of tool:

1. Review of literature on delay in the presentation and factors affecting it among breast cancer patients.

2. Preparation of the blue print of screening tool and self- structured tool.

3. Preparation of the first draft of tool.

4. Personal consultation and discussion with guide and co-guide.

5. Preparation of criteria rating scale for validation of tool.

6. Content validation of the tool.

7. Modifications of the tool based on suggestions.

8. Reliability testing of the tool.

9. Preparation of the final draft of tool.

Finalized tool for data collection included the following contents:

- Screening tool to select the participants for the research study based on inclusion and exclusion criteria. (ANNEXURE 1)
- Self – structured tool containing(ANNEXURE 2&3):

Section A: Socio-demographic and clinical characteristics.

This section included 9 items to assess the socio - demographic characteristics of the patients and 4 items to assess the clinical characteristics of the patients.

Socio-demographic data included:

- age, level of education, occupation, marital status, residence, number of children, religion, history of oral contraceptive pills use, socio economic status scale of Kuppuswamy.

Clinical data consisted of:

- first change of breast observed, family history of breast cancer, breast self-examination, comorbid disease

Section B: This section consisted 2 self-structured questions to assess presentation delay to the hospital among breast cancer patients.

Section C: This section comprised total 22 self-structured statements to assess factors affecting delayed presentation to the hospital among breast cancer patients categorized into 4 domains:

- physical factors : consisted of 4 statements
- knowledge factors : included 5 statements
- psychological factors :comprised of 9 statements
- socio-cultural factors : involved 4 statements.

- **Technique of data collection**

  In present study the screening tool based on inclusion and exclusion criteria was used to select the study participants and self- structured questionnaire was used as

technique of data collection. Face-to-face interview was conducted in which questions were read loudly and clearly to the participants by the researcher and responses were recorded accordingly.

- **Validity and Reliability of tools (ANNEXURE 5,6 & 7)**

Validity: Content validity of the self – structured tool was established. Tool was sent to 11 experts (ANNEXURE 4) in field of Medical – Surgical Nursing (9 experts) , Medical Oncology(1expert) and Department of Radiotherapy (1 expert). The Item Content Validity Index (I-CVI) and the Scale Content Validity Index (S-CVI) were computed.

- Section-A: socio -demographic data
    - S-CVI = (sum of I-CVI score/number of item)= 6.62/7 = 0.94
- Section-A: clinical Data
    - S-CVI = (sum of I-CVI score/number of item) = 3.9/4 = 0.97
- Section-B: presentation delay assessment
    - S-CVI = (sum of I-CVI score/number of item)= 2/2 = 1
- Section-C: factors affecting presentation delay
    - S-CVI = (sum of I-CVI score/number of item)= 20.9/21 = 0.99

The tool was found to be valid.

- **Reliability**: Reliability refers to the consistency and accuracy of an instrument with which it measures the target attribute for the purpose it is designed.(14)To establish the reliability of section C containing statements to assess factors affecting delay in presentation to the hospital among breast cancer patients, the self- structured questionnaire was administered on 15 breast cancer patients and

their response was collected. Internal consistency was calculated with split- half method using SPSS software (version 20). Split- half Correlation value (r) = 0.79 indicating acceptable level of reliability of the tool.[14]

- **Language translation:** The English-to-Hindi translation tool and its reverse translation were done and validated by experts in Hindi and English, respectively. (ANNEXURE 8 & 9)

Ethical considerations

Letter of permission taken from Institute Human Ethics Committee (LOP Ref. Number: AIIMS/BPL/IHECSR/JULY/22/MSc N/14) dated 28th February 2023. Administration permission was taken from Medical Superintendent, Principal-Nursing College, AIIMS Bhopal and notified HODs and Senior Nursing Officers of respective departments prior before commencing data collection (ANNEXURE 10). Participants were informed about the study using participant information sheet (ANNEXURE 11 & 12). Informed consent was taken from the study participants (ANNEXURE 13). Ensured anonymity by assigning code numbers for identification instead of using names. Upheld participant confidentiality by restricting data access to the research team exclusively.

Pilot study

Pilot study is the smaller scale study done before conducting actual main study. In present study pilot study was conducted in Oncology OPD, AIIMS Bhopal on 24/7/2023, 11/09/2023 and 13/9/2023 among 15 breast cancer patients after receiving permission from the medical superintendent. Using screening tool study participants were selected. Self-introduction was done and after establishing rapport with the subject purpose of the study was explained and consent was taken. Researcher asked questions to the subject and response was recorded in the questionnaire. This whole process took 20-25 minutes

for one patient. Pilot study revealed that the study was feasible and tool was suitable for use in the main study.

Procedure for data collection

After obtaining ethical clearance and permission from hospital authority data collection was commenced on 18th September 2023 and continued up to 8 November 2023. A written permission was obtained from the concerned authority prior to data collection. 138 breast cancer patients those are seeking treatment in AIIMS Bhopal were included. Study participants underwent screening using a screening tool, adhering to predetermined inclusion and exclusion criteria. Self-introduction was done and after establishing rapport with the participant, the purpose of the study was explained to each subject and a written consent was obtained from them. Then the final tool was administered through face-to-face interview and for each participant the whole process took 20- 25 minutes. Analytical procedures involved descriptive and inferential statistics to examine the collected data

Plan for data analysis

The data analysis plan incorporates both descriptive and inferential statistics. Master data sheet was prepared after editing, coding, tabulation for further analysis. Analysis of the data was conducted using IBM SPSS version 16.0.

- To check the normality of the delayed presentation time duration data Kolmogorov - Smirnov test was used. In the case of normally distributed data mean and standard deviation was calculated whereas if the data is not normally distributed median and range was analyzed.
- To describe the socio demographic and clinical variables frequency and percentage distribution was done.

- Frequency percentage distribution was analyzed to assess the time lag since first recognition of breast cancer symptom and presentation to the hospital among breast cancer patients.
- Frequency and percentage distribution along with multiple logistic regression analysis was used to identify the factors affecting delayed presentation to the hospital among breast cancer patient
- Chi square test/Fisher's exact test was used to find out the association between socio demographic and clinical variables with delay in presentation to the hospital among breast cancer patients. Fisher's exact test was performed wherever more than 20% of cell have expected frequencies <5.

CHAPTER IV

RESULTS

CHAPTER 4

RESULTS

This chapter focuses on the analysis and interpretation of data obtained from breast cancer patients attending the oncology outpatient department (OPD) through self-structured questionnaire. The collected data was analysed using descriptive and inferential statistical methods according to the objectives and hypotheses of the study. The statistical analysis was carried out utilizing IBM SPSS version 16.0.

Organization of the study findings-

The findings of the present study are organized under the following headings:

SECTION – I (a): Description of socio-demographic variables of breast cancer patients.

SECTION – I (b): Description of clinical variables of breast cancer patients.

SECTION – II: Delay in presentation to the hospital among breast cancer patients.

SECTION – III: Description of factors affecting delayed presentation to the hospital among breast cancer patients.

SECTION – IV (a): Univariate binary logistic regression to find out the factors affecting delayed presentation to the hospital among breast cancer patients.

SECTION – IV (b): Multiple binary logistic regression to find out the factors affecting delayed presentation to the hospital among breast cancer patients.

SECTION – V (a): Association of socio- demographic variables with delay in presentation to the hospital among Breast Cancer patients.

SECTION – V (b): Association of Clinical variables with delay in presentation to the hospital among Breast Cancer patients.

SECTION – I (a)

Description of Socio-demographic variables of breast cancer patients

Table 1: Frequency and percentage distribution of participants according to their socio demographic variables.

(N = 138)

Sl. No.	Socio-demographic variables		Frequency	Percentage
1.	**Age in years**	18 – 28	2	1.4%
		29 – 39	26	18.8%
		40 – 50	60	43.5%
		51 – 60	50	36.2%
2.	**Level of education**	Unable to read and write	36	26.1%
		Primary education and less	25	18.1%
		Secondary education	41	29.7%
		Higher secondary education	11	8.0%
		College and above	25	18.1%
3.	**Occupation**	Housewife	108	78.3%
		Government employee	8	5.8%
		Private employee	5	3.6%
		Have own business	7	5.1%
		Other	10	7.2%
4.	**Marital status**	Unmarried	2	1.4%
		Married	124	89.9%
		Divorced	1	0.7%
		Widowed	11	8.0%
5.	**Residence**	Rural area	67	48.6%
		Urban area	71	51.4%

Table 1 contd.: Frequency and percentage distribution of participants according to their socio demographic variables.

(N = 138)

Sl. No.	Socio-demographic variables		Frequency	Percentage
6.	**Number of children**	Nil	4	2.9%
		1	8	5.8%
		2	64	46.4%
		3	37	26.8%
		>3	25	18.1%
7.	**Religion**	Hindu	122	88.4%
		Muslim	13	9.4%
		Christian	0	0%
		Other	3	2.2%
8.	**History of Oral Contraceptive Pills use**	Yes	11	8.0%
		No	127	92.0%
9.	**Socio- economic status**	Upper	2	1.4%
		Upper middle	8	5.8%
		Lower middle	42	30.4%
		Upper lower	80	58.0%
		Lower	6	4.3%

The above table 1 described the distribution of participants according to their socio demographic variables. 60 (43.50%), fell within the age range of 40 to 50 years. This was followed by those aged 51 to 60 years i.e. 50 (36.20%). 41 (29.7%) participants studied till Secondary education, followed by 36 (26.1%) participants are unable to read and write. 108 (78.3%) participants were housewife. 71 participants (51.4%) live in urban areas. 122 (88.4%) respondents were Hindu. Majority of the respondents i.e. 127 (92.0%) had no history of any Oral contraceptive pills use. 80 (58%) of the participants, belong to the upper lower class. Following this, an average of 31% of participants fall into the lower middle-class category.

SECTION – I (b)
Description of Clinical variables of breast cancer patients

Table 2: Frequency and percentage distribution of participants according to their clinical variables.

(N= 138)

SL. NO.	Clinical variables		Frequency	Percentage
1.	**First change of breast observed**	Breast Lump	106	76.8%
		Swelling under axilla / palpable axillary lymph nodes	6	4.3%
		Breast pain	10	7.2%
		Tingling	4	2.9%
		Nipple problems/ Abnormal Discharge per nipple	8	5.8%
		Two breasts are not equal in size or shape	2	1.4%
		Breast dimpling	2	1.4%
		Other	0	0%
2.	**Family history of breast cancer**	Yes	9	6.5%
		No	129	93.5%
3.	**Breast self-examination**	At least once a month	3	2.2%
		Every 3 month	0	0%
		Rarely or never	135	97.8%
4.	**Hypertension**	Yes	18	13.0%
		No	120	87.0%
5.	**Diabetes**	Yes	12	8.7%
		No	126	91.3%
6.	**Tuberculosis**	Yes	1	0.7%
		No	137	99.3%

Table 2 contd.: Frequency and percentage distribution of participants according to their clinical variables.

(N= 138)

SL. NO.	Clinical variables		Frequency	Percentage
7.	**Cardiac disease**	Yes	1	0.7%
		No	137	99.3%
8.	**Other (Asthma)**	Yes	3	2.2%
		No	135	97.8%
9.	**Other (Thyroid disorders)**	Yes	8	5.8%
		No	130	94.2%
10.	**No comorbid illness**	Yes	102	73.9%
		No	36	26.1%

The table 2 above shows that the most prevalent initial change observed in the breast was a breast lump, accounting for an average percentage of 77%, i.e., 106 out of 138 participants. Majority of respondents i.e. 129 (93.50%) had no family history of breast cancer patients. Only 3 (2.2%) participants performed breast self-examinations at least once a month, while the majority of respondents, 135 (97.8%), rarely or never did in breast self-examination. Among the participants, 102 (73.9%) did not had any comorbid illnesses.

SECTION – II
Delay in presentation to the hospital among breast cancer patients

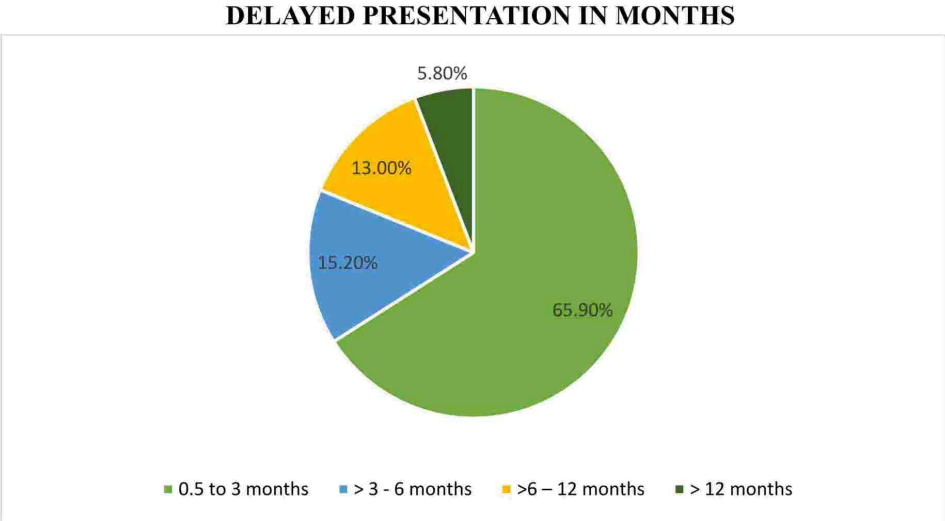

Figure 2: Percentage distribution of delay in the presentation to the hospital among breast cancer patients (N = 138)

The pie chart in figure 2 above shows that **o**ut of 138 participants, 91 (64.9%), experienced a delay in presenting to the hospital within 0.5 to 3 months, while 21 (15.2%) participants presented their symptoms in between >3 - 6 months. 18 (13.0%) participants presented in between >6 – 12 months and only 8 (5.8%) participants presented after 12 months.

Table 3 : Median and range of Presentation delay among Breast Cancer patients.

(N = 138)

Variable	**MEDIAN**	**RANGE**
Presentation Delay	2 months	15 days – 3 years

The table 3 above indicates that the median delay in presentation to the hospital was 2 months, with a range spanning from 15 days to 3 years.

SECTION – III

Description of factors affecting delayed presentation to the hospital among breast cancer patients

Table 4: Frequency and percentage distribution of factors affecting delayed presentation to the hospital among breast cancer patients.

(N = 138)

Sl. No.	Variables		Frequency	Percentage
Physical Factor				
1.	There was no diagnostic/ treatment facility near me.	Yes	24	17.4%
		No	114	82.6%
2.	I was too busy in my household chores/ job.	Yes	45	32.6%
		No	93	67.4%
3.	Breast Lump was too small.	Yes	69	50.0%
		No	69	50.0%
4.	The symptoms were not causing any pain or discomfort for me.	Yes	105	76.1%
		No	33	23.9%
Knowledge Factor				
5.	I didn't know where to go for consultation for these observed breast changes.	Yes	17	12.3%
		No	121	87.7%
6.	I thought it is due to pregnancy/ effect of lactation.	Yes	3	2.2%
		No	135	97.8%
7.	I didn't have knowledge about Breast Cancer.	Yes	120	87.0%
		No	18	13.0%
8.	I thought it will be relieved by itself.	Yes	89	64.5%
		No	49	35.5%

Table 4 CONTD.: Frequency and percentage distribution of factors affecting delayed presentation to the hospital among breast cancer patients.

(N = 138)

Sl. No.	Variables		Frequency	Percentage
9.	I thought it was not serious and didn't require medical attention.	Yes	101	73.2%
		No	37	26.8%
Psychological Factors				
10.	I was afraid what others will think about it.	Yes	13	9.4%
		No	125	90.6%
11.	I was embarrassed to talk about my breast condition to others.	Yes	23	16.7%
		No	115	83.3%
12.	I was afraid to going out due to COVID-19 pandemic.	Yes	7	5.1%
		No	131	94.9%
13.	It doesn't want to accept my condition/ Denial.	Yes	7	5.1%
		No	131	94.9%
14.	I had fear of husband abandonment.	Yes	0	0%
		No	138	100.0%
15.	I was afraid of possible diagnosis of Cancer or any severe illness.	Yes	9	6.5%
		No	129	93.5%
16.	I was afraid of the treatment.	Yes	7	5.1%
		No	131	94.9%
17.	I didn't had trust on health care system.	Yes	1	0.7%
		No	137	99.3%
18.	I had fear that I might die.	Yes	1	0.7%
		No	137	99.3%
Socio-Cultural Factors				
19.	My religion didn't allow me to take medical consultation about this condition.	Yes	1	0.7%
		No	137	99.3%
20.	I sought alternative treatment first for these symptoms.	Yes	26	18.8%
		No	112	81.2%
21.	I was concerned about the cost for the treatment.	Yes	20	14.5%
		No	118	85.5%
22.	Any other (Lack of family support)	Yes	10	7.2%
		No	128	92.8%

The table 4 above shows that under physical factors ,105 (76.1%) respondents did not have any pain or discomfort and 69 (50.0%) respondents had small breast lump therefore they had delay in presenting the symptoms to the hospital. Under knowledge factor, 120 (87.0%) respondents did not had knowledge about breast cancer and 101 (73.2%) respondents thought that the symptoms are not serious and did not require medical attention therefore they had delay in presentation to the hospital. Under psychological factors, 23 (16.7%) participants were embarrassed to talk about their condition to others resulting in delayed presentation to the hospital. Under Socio – cultural factors, 26 (18.8%) participants sought alternative treatment first and 20 (14.5%) participants were concerned about the cost for the treatment that results in late presentation to the hospital. While specifying " Any other" 10 participants stated that they lack support from the family members resulting in delayed presentation to the hospital.

SECTION – IV (a)
Univariate binary logistic regression to find out the factors affecting delayed presentation to the hospital among breast cancer patients

$H0_1$: There is no significant association between delay in presentation to the hospital and factors affecting delayed presentation to the hospital among breast cancer patients.

To fit a regression model, a sample size of 10 per independent variable is required. As the sample size of the study is 138, 13 independent variables were included in the regression analysis.

Table 5: Univariate binary logistic regression analysis to find out the factors affecting delayed presentation to the hospital among breast cancer patients.

(N = 138)

SL. NO.	Variables	Odds Ratio (OR)	Confidence Interval		p value
			Lower	Upper	
1.	There was no diagnostic/ treatment facility near me.	2.217	0.771	6.373	0.140
2.	I was too busy in my household chores/ job.	0.705	0.326	1.523	0.374
3.	Breast Lump was too small.	2.702	1.298	5.625	0.008*
4.	The symptoms were not causing any pain or discomfort for me.	1.251	0.538	2.909	0.602
5.	I didn't know where to go for consultation for these observed breast changes.	1.869	0.670	5.213	0.232
6.	I didn't have knowledge about Breast Cancer.	2.895	0.794	10.558	0.107
7.	I thought it will relief by itself.	1.712	0.797	3.678	0.168
8.	I thought it was not serious and didn't require medical attention.	1.877	0.800	4.400	0.148
9.	I was afraid what others will think about it.	2.479	0.782	7.856	0.123

Table 5 CONTD.: Univariate binary logistic regression analysis to find out the factors affecting delayed presentation to the hospital among breast cancer patients.

(N = 138)

SL. NO.	Variables	Odds Ratio (OR)	Confidence Interval		p value
10.	I was embarrassed to talk about my breast condition to others.	2.494	1.004	6.191	0.049*
11.	I sought alternative treatment first for these symptoms.	1.031	0.420	2.530	0.947
12.	I was concerned about the cost for the treatment.	1.722	0.658	4.507	0.268
13.	Lack of family support.	2.169	0.442	10.650	0.080

*Indicates significant at $p<0.05$

The results in Table 5 revealed that factors “Breast Lump was too small” and “I was embarrassed to talk about my breast condition to others” are statistically significant (p value <0.05) and hence a multiple logistic regression was fit.

SECTION – IV (b)
Multiple binary logistic regression to find out the factors affecting delayed presentation to the hospital among breast cancer patients

The variables which were found statistically significant in univariate binary logistic regression analysis were taken for multiple binary logistic regression.

Table 6: Multiple binary logistic regression analysis to find out the factors affecting delayed presentation to the hospital among breast cancer patients.

(N = 138)

SL. NO.	Variables	Adjusted Odds Ratio (AOR)	Confidence Interval		p value
			Lower	Upper	
1.	Breast Lump was too small.	0.386	0.184	0.810	0.012*
2.	I was embarrassed to talk about my breast condition to others.	0.434	0.171	1.104	0.080

*Indicates significant at $p<0.05$

Based on the results of multiple logistic regression (Table 6), $H0_1$ is only rejected for the factor "Breast Lump was too small". Therefore, it was concluded that factor "Breast Lump was too small" is a statistically significant factor associated with delay (p value=0.012), after adjusting for the effect of factor "I was embarrassed to talk about my breast condition to others".

It depicts that delay in presentation to the hospital is less likely i.e. 0.386 times (OR = 0.386) for those who had comparably larger breast lump compared to those who had small breast lump.

SECTION – V (a)
Association of socio- demographic variables with delay in presentation to the hospital among Breast Cancer patients.

$H0_2$: There is no significant association between socio-demographic variables and clinical variables and delay in presentation to the hospital among breast cancer patients.

Table 7: Association of socio-demographic variables with delay in presentation to the hospital among Breast cancer patients with frequency and percentage distribution.

(N = 138)

Sl. No.	Socio-demographic variables		Delay in the presentation				p value
			0.5 to 3 months (n = 91)		> 3 months (n = 47)		
			f	%	f	%	
1.	Age in years##	18- 39	19	67.9%	9	32.1%	0.762
		40- 50	41	68.3%	19	31.7%	
		51- 60	31	62.0%	19	38.0%	
2.	Level of Education##	Unable to read and write	27	75.0%	9	25.0%	0.093
		Primary education and less	12	48.0%	13	52.0%	
		Secondary education	30	73.2%	11	26.8%	
		Higher secondary education	5	45.5%	6	54.5%	
		College and above	17	68.0%	8	32.0%	
3.	Occupation status##	Housewife	70	64.8%	38	35.2%	0.596
		Other	21	70.0%	9	30.0%	
4.	Marital status#	Unmarried	10	71.4%	4	28.6%	0.772
		Married/Divorced/Widowed	81	65.3%	43	34.7%	

Table 7 CONTD. : Association of socio-demographic variables with delay in presentation to the hospital among Breast cancer patients with frequency and percentage distribution.

(N = 138)

Sl. No.	Socio-demographic variables		Delay in the presentation				p value
5.	**Residence**[##]	Rural area	43	64.2%	24	35.8%	0.671
		Urban area	48	67.6%	23	32.4%	
6.	**Number of children**[#]	Nil	2	50%	2	50%	0.951
		1	5	62.5%	3	37.5%	
		2	42	65.6%	22	34.4%	
		3	25	67.6%	12	34.4%	
		4	17	68.0%	8	32.0%	
7.	**History of OCP use**[#]	0	84	66.1%	43	33.9%	0.999
		1	7	63.6%	4	36.4%	

*Indicates significant at $p<0.05$

[#]Indicates that analysis of the variable was done using Fisher's exact test because more than 20% of cells have expected frequency <5.

[##] Indicates that analysis of the variable was done using Chi Square test.

The test of association in table 7 revealed that, $H0_2$ is accepted for all socio – demographic variables. There is no statistically significant association exists between delay in presentation to the hospital among breast cancer patients and socio – demographic variables.

SECTION – V (b)
Association of clinical variables with delay in presentation to the hospital among breast cancer patients

Table 8: Association of clinical variables with delay in presentation to the hospital among Breast Cancer patients with frequency and percentage distribution.

(N = 138)

Sl. No.	Clinical variables		Delay in the presentation				p value
			0.5 to 3 months (n = 91)		> 3 months (n = 47)		
			f	%	f	%	
1.	First change of breast observed##	Breast Lump	65	61.3%	41	38.7%	0.037*
		Other	26	81.2%	6	18.8%	
2.	Family history of breast cancer#	Yes	6	66.7%	3	33.3%	0.999
		No	85	65.9%	44	34.1%	
3.	Breast self-examination#	At least once a month	3	100%	0	0%	0.551
		Rarely or never	88	65.2%	47	34.8%	
4.	Hypertension##	Yes	13	72.2%	5	27.8%	0.547
		No	78	65.0%	42	35.0%	
5.	Diabetes#	Yes	10	83.3%	2	16.7%	0.221
		No	81	64.3%	45	35.7%	
6.	Other#	Yes	8	72.7%	3	27.3%	0.749
		No	83	65.4%	44	34.6%	
7.	No comorbid illness##	Yes	65	63.7%	37	36.3%	0.355
		No	26	72.2%	10	27.8%	

*Indicates significant at $p<0.05$

#Indicates that analysis of the variable was done using Fisher's exact test because more than 20% of cells have expected frequency <5.

Indicates that analysis of the variable was done using Chi Square test.

From table 8, $H0_2$ a is rejected for the selected clinical variables. There is statistically significant association exists between delay in presentation to the hospital and the type of change in breast first observed (p=0.037). i.e. 38.7% of breast cancer patients who delayed for more than 3 months observed breast lump as the first change in breast whereas this proportion was 61.3% among the patients who delayed for 3 months or less.

CHAPTER V

DISCUSSION

CHAPTER 5

DISCUSSION

This chapter provides a concise discussion about major findings, strengths and limitations of the study, along with implication and recommendations.

Major findings of the study are discussed under the following categories:

SECTION I: Description of socio – demographic variable of breast cancer patients.

SECTION II: Description of clinical variable of breast cancer patients.

SECTION III: Delay in presentation to the hospital among breast cancer patients.

SECTION IV: Factors related to delay in presentation related to the hospital among breast cancer patients.

SECTION V: Association of socio – demographic and clinical variables with delay in the presentation to the hospital.

SECTION I

Description of socio – demographic variable of breast cancer patients

- The largest proportion of breast cancer patients, accounting for 43.5%, fell within the age range of 40 to 50 years, with the second-highest group, comprising 36.2%, falling between 51 and 60 years of age.
- Out of 138 participants, 29.7%, attained a secondary education, while 26.1% of participants were unable to read and write.
- 78.3% were housewives.

- A total of 124 participants (89.9%) were married, with 11 (8.0%) were divorced, and only 2 (1.4%) were unmarried.
- There was nearly an equal distribution between participants from rural and urban areas, accounting for 48.6% (67 participants) and 51.4% (71 participants) respectively.
- Out of 138 study participants 88.4%, belonged to Hindu religion.
- Majority of the respondents i.e. 127 (92.0%) had no history of oral contraceptive pills use.
- 80 participants (58%) belonged to the upper lower class and around 30.4% of participants to the lower middle-class.

SECTION II

Description of clinical variable of breast cancer patients

- First symptom observed among 76.8% of patients was breast lump , with breast pain observed in 7.2% of individuals as a subsequent symptom.
- The majority of respondents, specifically 93.50% (129 participants), did not have a family history of breast cancer.
- Majority of the respondents; 97.8%, rarely or had never done breast self-examination.
- 102 (73.9%) participants did not have any comorbid illness.

SECTION III

Delay in presentation to the hospital among breast cancer patients

- Median delay in presentation to the hospital was 2 months, with a range spanning from 15 days to 3 years.
-

SECTION IV

Factors affecting delay in presentation related to the hospital among breast cancer patients

- Breast cancer patients who had smaller breast lump are more likely to delay in the presentation to the hospital.

SECTION V

Association of socio – demographic and clinical variables with delay in the presentation to the hospital

- A statistically significant association exists between delay in presentation to the hospital and the type of change in breast first observed (p=0.037).

Discussion

The present study collected information from 138 breast cancer females attending Oncology Outpatient department (OPD) at All India Institute of Medical Sciences (AIIMS), Bhopal about the time they had taken to present their initial breast cancer related symptoms to the medical personnel. The median duration of delayed presentation was 2 months with a range of 15 days to 3 years. The statistically significant factor identified using multiple binary logistic regression was "breast lump was small" resulting in delayed presentation (p = 0.012). Delay for longer than three month was found in 34.1% of the women. Socio demographic factors were not statistically associated with delayed presentation to the hospital whereas clinical variable i.e. first breast change observed is found to be significantly associated with delayed presentation to the hospital (p = 0.037). In our study, 43.5% of respondents were between the age of 40 to 50 years and reported delay in seeking medical attention. Similar findings of a high number of cases occurring

between the age of 41 - 49 years were observed in two previously conducted Indian studies.[9,22] In present study, only 2.2% participants performed breast self-examination at least once a month and one study also noted similar finding where few participants reported performing breast self-examination.[30]

Breast lump was the most common first breast change observed by the patients in the present study and across the globe[20,22,26-31,33] ,and higher delay was significantly ($p = 0.037$) observed in the present study in those patients who had breast lump as their initial symptom compared to those who had other symptoms. Consistent results were observed in few studies[30,31] and contrast results of no significant association between initial breast change with delayed presentation was seen in an Indian [22] and a Malaysian[33] study. A common assumption was that breast lump was small or not causing any discomfort to them, therefore medical attention is not required. Few also misinterpret the breast lump with other non-serious disease condition that results in delayed presentation as they waited for the lump to heal by itself. Similar finding of breast pain being the second most common first breast change observed was found in studies conducted in India.[22,28,29]

A median delay of 2 month was observed was observed in the present study is consistent with the findings of two additional studies.[19,25] In contrast, some studies have demonstrated a median delay larger than that observed in the present study.[9,22,30] 34.1% participants delayed presentation >3 months in the present study. Contradictory finding of slightly greater percentage of > 3-month presentation of patients was reported in several research projects.[18,27,30-32] Delayed presentation of over six months was found to be 18.8% in present study whereas it is significantly higher, approximately 50%, in one Indian study,[9] while it was comparatively lower in another Indian study.[30]

Factors affecting the delayed presentation were identified in the present study among participants. Upon searching for reports regarding the reasons for delay, consistent with other studies [26,29,32], the predominant factor contributing to delayed presentation was lack of awareness or knowledge about breast cancer. Awareness of cancer symptoms has been linked to increased attention to those symptoms and a reduced expected delay in seeking help.[38] Similar findings to those of the current study were observed with comparable percentages under certain factors contributing to delayed hospital presentation like perception that symptoms did not signify a serious condition, the belief that symptoms would resolve over time, social stigma and financial constraints.[30] Under psychological factors, embarrassment and fear of others judgment was the most common factor for delayed presentation in the present study. The perpetuation of such stigma can be contributed by the misunderstandings about the disease and the patriarchal dynamics within society, particularly in rural settings where women often rely on men for their healthcare.[34-35] In the present study under socio-cultural factors, a common reason for delaying presentation was the first preference for alternative treatments, which included home remedies, spiritual approaches, herbal medicine, massage, etc. Consistent finding was seen in a study conducted in 2022.[33] Patients often waited for their symptoms to subside by relying on these alternative therapies. While there is a lack of conclusive evidence regarding the effectiveness of alternative therapies in treating cancer, they often appeal to patients due to assertions of "minimal side effects" and convenient/affordable accessibility.[36]

In the present study, multiple logistic regression revealed that smaller breast lump is significantly more likely to cause delay compared to those who had larger breast lump, whereas other factors included in the study were not found significantly affecting delayed

presentation. Similarly, a Malaysian study observed breast lump as most common symptom of respondents and concluded that the main reason for seeking care was that the breast lump was getting bigger.[33] In contrast, factors that were not significantly associated with delay in the present study were, however, found to be significantly associated with delayed presentation in other Indian and Malaysian studies, these factors encompassed the lack of knowledge[26] or awareness[30] about Breast cancer, adoption of alternative treatments [30], perceiving symptoms as non-serious and painless [20], and the belief that symptoms were not dangerous.[33]

There was no significant association found between socio-demographic variables and delayed presentation to the hospital. Similar findings of age, [20,28] residence [28] and socio-economic status [20,28] not being significantly associated with delay was reported in few studies. In line to the present study socio – economic status was not found significantly associated with delay in north east India and Gaza. [9,20,28-29] Meanwhile, the tendency for the older age group to seek healthcare later is reported in studies conducted by Thakur et al. and Shah P et al..[9,29] Abdulkareem et al.'s study indicated that younger females tended to wait longer than their older counterparts, and rural women, along with those with lower levels of education, were at a higher risk of delayed presentation [31.]

Strengths of the study

1. Study findings will be helpful in developing future interventions related to breast cancer to prevent delay in presentation to the hospital.
2. Study included multiple possible factors which can affect the delay in presentation to the hospital among breast cancer patients,

3. Adequate time was taken while collecting the information from each patient in order to find out the time lag and the factors which can affect the delay in presentation to the hospital among breast cancer patients.
4. Patients were given the freedom to select multiple factors contributing to the delay in presentation, each of which they considered most significant.

Limitations of the study

1) Only one setting was involved in this study.
2) Subjective evaluation was for assessing delayed presentation to the hospital time lag.
3) Possible chances of recall bias.

Implication of the study

1. Community outreach programs can be developed for the target population group to receive health education about warning symptoms of breast cancer to prevent delayed presentation to the hospital.
2. In nursing research, qualitative study can be done for in depth assessment of factors associated with delay in presentation to the hospital among breast cancer patients.

Recommendations

1. More emphasis can be laid on importance of health education regarding Breast Self-Examination and awareness related to breast cancer and the necessity for individuals to seek early medical attention for improved management.
2. Conducting similar studies as multicentric research with a larger sample size and an extended time frame is valuable, especially considering the scarcity of such research in India.

Conclusion

Breast cancer is a prevalent cancer. The significant worry lies in delays in seeking medical attention and the tendency for individuals to present at advanced stages. The results of the study suggest that considerable number of patients experienced a small breast lump as a significant reason for the presentation delay. Therefore, better screening strategy related services for early identification can be provided and future awareness campaigns should highlight that any breast symptom have potential to be associated with breast cancer, which may help in reducing percentage of delayed presentation and further increase quality of life of the patients.

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ANNEXURE

ANNEXURE 1

SCREENING TOOL

SCREENING TOOL

1. DATE OF ASSESSMENT ……
2. AGE(in years) ……
3. Diagnosis ……
4. Are you able to understand Hindi or English? [Yes/No]

   ……
5. What is the duration between first detection of the breast cancer related symptoms and first medical interaction?

   ……
6. Did you had history of any other site cancer or recurrence of breast cancer in the there?

   ……
7. Is the patient diagnosed with any psychological problem or cognitive impairment and unable to give response to the questions ? (Yes/No)

   ……..
8. Are you willing to participate in the study?

   …….

SELECTED FOR THE STUDY - [ ] YES [ ] NO

1. PATIENT NAME ……..
2. CODE NO. ……
3. PLACE OF SCREENING ……..
4. CONTACT NUMBER ……...
5. ADDRESS ……

ANNEXURE 2

DATA COLLECTION TOOL (ENGLISH)

Code No. …….

Tool for data collection

SECTION A : Questionnaire to assess social demographic and clinical data

Instructions: Kindly tick(✓) the most appropriate answer for each item. The information provided by you will be kept confidential and will only be used for research purpose.

SOCIO-DEMOGRAPHIC DATA OF THE BREAST CANCER PATIENT

1. Age group (in years)…….

2. Level of education…….

a. Unable to read and write ( )

b. Primary education and less. ( )

c. Secondary education ( )

d. Higher secondary education ( )

e. College and above ( )

3. Occupation status…….

a. Housewife ( )

b. Government employee ( )

c. Private employee ( )

d. Have own business ( )

e. Other(specify) ( )……

4. Marital status……...

a. Unmarried ( )

b. Married ( )

c. Divorced ( )

d. Widowed ( )

5. Residence…….

a. Rural area ( )

b. Urban area ( )

6. If married, Number of children……

a. Nil ( )
b. 1 ( )
c. 2 ( )
d. 3 ( )
e. >3 ( )

7. Religion……...

a. Hindu ( )

b. Muslim ( )

c. Christian ( )

d. Other (specify) ( )……

8.. Is there any history of oral contraceptive pills use, if yes; what is the duration?

……

SOCIO- ECONOMIC STATUS SCALE OF KUPPUSWAMY

1. Education of the Head

Variable	Answer
a. Profession or honours	
b. Graduate	
c. Intermediate or diploma	
d. High school	
e. Middle school	
f. Primary school	
g. Illiterate	

2. Occupation of Head of the family

Variable	Answer
a. Professionals	
b. Semi- professional	
c. Clerical/Shop/ Farmer	
d. Skilled workers	

e. Semi- skilled workers	
f. Unskilled Worker	
g. Unemployed	

3. Total monthly income of the family

Variable	Answer
a. Equal to more than 185,895	
b. 92,951 – 185,894	
c. 69,535 – 92,950	
d. 46,475 – 69,534	
e. 27883 – 46474	
f. 9308 – 27882	
g. less than or equal to 9307	

CLINICAL DATA

VARIABLES	CATEGORY
1. What is First change of breast is observed?	○ Breast Lump ○ Swelling under axilla / palpable axillary lymph nodes ○ Breast pain ○ Tingling ○ Nipple problems/ Abnormal Discharge per nipple ○ Two breast are not equal in size or shape ○ Breast dimpling ○ Other

2. Do you have Family history of breast cancer?	○ Yes If yes, what is the relation?..... ○ No
3. How frequently you perform Breast self-examination?	○ At least once a month ○ Every 3 month ○ Rarely or never (Rarely = <2 times a year)
4. Do you have any Comorbid disease, if yes what is the time period of comorbid illness?	○ HTN, if yes, duration…… ○ Diabetes, if yes, duration……. ○ TB, if yes, duration……... ○ Cardiac disease, if yes, duration……... ○ Other(specify)…… ○ No comorbid illness

SECTION B : QUESTIONNAIRE TO ASSESS PRESENTATION DELAY

Instructions: Kindly write the most appropriate answer for each item. The information provided by you will be kept confidential and will only be used for research purpose.

1. When did you first observe the above-mentioned symptoms about breast cancer? ……
2. What is the duration between the first time you noticed changes in your breasts and the first time you visited a medical health facility?

   ……(days/ week/month/year)

SECTION C : QUESTIONNAIRE TO ASSESS FACTORS AFFECTING DELAYED PRESENTATION

Instructions:

Dear participant, following are the statement related to the factors which affect delayed presentation. The available response for each statement is "YES" or "NO". Tick (✓)" YES" or "NO" in the space given, at the given statement is related to you then tick "YES", if not then tick "NO". Kindly tick(✓) the most appropriate answer for each item. The information provided by you will be kept confidential and will only be used for research purpose.

STATEMENT	YES	NO
Physical Factor		
1. There was no diagnostic/ treatment facility near me.		
2. I was too busy in my household chores/ job.		
3. Breast Lump was too small.		
4. The symptoms were not causing any pain or discomfort for me.		
Knowledge Factor		
5. I didn't know where to go for consultation for these observed breast changes.		
6. I thought it is due to pregnancy/ effect of lactation.		
7. I didn't have knowledge about Breast Cancer.		
8. I thought it will relieved by itself.		
9. I thought it was not serious and didn't require medical attention.		
Psychological Factors		
10. I was afraid what others will think about it.		
11. I was embarrassed to talk about my breast condition to others.		
12. I was afraid to going out due to COVID-19 pandemic.		
13. I don't want to accept my condition/ Denial.		
14. I had fear of husband abandonment.		
15. I was afraid of possible diagnosis of Cancer or any severe illness.		
16. I was afraid of the treatment		
17. I didn't had trust on health care system.		

18. I had fear that I might die.		
Socio-Cultural Factors		
19. My religion didn't allow me to take medical consultation about this condition		
20. I sought alternative treatment first for these symptoms.		
21. I was concerned about the cost for the treatment.		
22. Any other (specify)…….		

ANNEXURE 3

DATA COLLECTION TOOL (HINDI)

कोड संख्या। .....

डेटा संग्रह के लिए उपकरण

अनुभाग ए: सामाजिक जनसांख्यिकीय और नैदानिक डेटा का आकलन करने के लिए प्रश्नावली

निर्देश: कृपया प्रत्येक आइटम के लिए सबसे उपयुक्त उत्तर पर (✓) निशान लगाएं। आपके द्वारा प्रदान की गई जानकारी गोपनीय रखी जाएगी और इसका उपयोग केवल शोध उद्देश्य के लिए किया जाएगा।

स्तन कैंसर रोगी का सामाजिक-जनसांख्यिकीय डेटा

1. आयु (वर्षों में).....

2. शिक्षा का स्तर.....।

a. लिखने और पढ़ने में असमर्थ ( )
b. प्राथमिक शिक्षा एवं कम ( )
c. माध्यमिक शिक्षा ( )
d. उच्च माध्यमिक शिक्षा ( )
e. कॉलेज और ऊपर ( )

3. व्यवसाय की स्थिति.....

a. गृहिणी ( )
b. सरकारी कर्मचारी ( )
c. निजी कर्मचारी ( )
d. अपना व्यवसाय ( )
e. अन्य (निर्दिष्ट करे)( ).....

4. वैवाहिक स्थिति.....

a. अविवाहित ( )
b. विवाहित ( )
c. तलाकशुदा ( )
d. विधवा ( )

5. निवास स्थान.....।

a. ग्रामीण क्षेत्र ( )
b. शहरी क्षेत्र ( )

6. यदि विवाहित हैं तो बच्चों की संख्या...

a 0 ( )
b 1( )
c 2( )
d 3 ( )
e >3 ( )

7. धर्म.....

a. हिंदू ( )
b. मुस्लिम ( )
c. ईसाई ( )
d. अन्य (निर्दिष्ट करे)( ).....

8. क्या मौखिक गर्भनिरोधक गोलियों के उपयोग का कोई इतिहास है, यदि हाँ; तो उसके इस्तेमाल की अवधि क्या है?

.....

कुप्पुस्वामी का सामाजिक-आर्थिक स्थिति पैमाना

1. मुखिया की शिक्षा

चर	उत्तर
a व्यवसाय या ऑनर्स	
b ग्रेजुएट	
c इंटरमीडिएट या डिप्लोमा	
d उच्च विद्यालय	
e मिडिल स्कूल	
f प्राथमिक स्कूल	
g निरक्षर	

2. परिवार के मुखिया का व्यवसाय

चर	उत्तर
a व्यवसायिक	
b अर्ध- व्यवसायिक	

c लिपिक/दुकान/किसान	
d कुशल श्रमिक	
e अर्ध-कुशल श्रमिक	
f अनिपुण कामगार	
g बेरोज़गार	

3. परिवार की कुल मासिक आय

चर	उत्तर
a. 185,895 से अधिक के बराबर	
b. 92,951 – 185,894	
c. 69,535 - 92,950	
d. 46,475 – 69,534	
e. 27,883-46,474	
f. 9,308-27,882	
g. 9,307 से कम या उसके बराबर	

चिकित्सीय आंकड़े

चर	वर्ग
1. स्तन में पहला परिवर्तन आपने क्या देखा ?	○ स्तन की गांठ ○ कांख/स्पर्शीय कांख लिम्फ नोड्स के नीचे सूजन ○ छाती में दर्द ○ झुनझुनी ○ निपल की समस्याएं/प्रति निपल से असामान्य बहाव ○ दोनों स्तनों के आकार में समानता नहीं थी

	○ स्तन में गड्ढा पड़ना ○ अन्य.....
2. क्या आपके परिवार में स्तन कैंसर का इतिहास है?	○ हाँ यदि हां, तो उनसे आपका क्या संबंध है?..... ○ नहीं
3. आप कितनी बार स्वयं स्तन परीक्षण करते हैं?	○ कम से कम महीने में एक बार ○ हर 3 महीने में ○ शायद ही कभी या कभी नहीं (शायद ही कभी = <2 बार प्रति वर्ष)
4. क्या आपको कोई सह-रुग्ण रोग है, यदि हाँ तो सह-रुग्ण रोग की समयावधि क्या है?	○ BP जायदा रहना, यदि हाँ, अवधि..... ○ मधुमेह, यदि हां, तो अवधि..... ○ टीबी, यदि हां, अवधि..... ○ हृदय रोग, यदि हाँ, अवधि..... ○ अन्य (निर्दिष्ट करे)..... ○ कोई सहवर्ती बीमारी नहीं

खंड बी: प्रस्तुति में देरी का आकलन करने के लिए प्रश्नावली

निर्देश : कृपया प्रत्येक प्रश्न के लिए सबसे उपयुक्त उत्तर लिखें। आपके द्वारा प्रदान की गई जानकारी गोपनीय रखी जाएगी और इसका उपयोग केवल शोध उद्देश्य के लिए किया जाएगा।

1) कब आप पहली बार स्तन कैंसर के बारे में ऊपर बताए गए लक्षणों को देखते हैं?

.....

2) पहली बार जब आपने अपने स्तनों में परिवर्तन देखा और पहली बार किसी चिकित्सा स्वास्थ्य सुविधा का दौरा किया, उसके बीच की अवधि का समय5 क्या है?

.....(दिन/सप्ताह/माह/वर्ष)

<u>अनुभाग सी</u>:

विलंब को प्रभावित करने वाले कारकों का आकलन करने के लिए प्रश्नावली प्रस्तुति

निर्देश:

प्रिय प्रतिभागी, विलंबित प्रस्तुति को प्रभावित करने वाले कारकों से संबंधित कथन निम्नलिखित हैं। प्रत्येक कथन के लिए उपलब्ध प्रतिक्रिया 'हाँ' या 'नहीं' है। दिए गए स्थान पर (✓) 'हाँ' या 'नहीं' पर टिक करें, यदि दिया गया कथन आपसे संबंधित है तो 'हाँ' पर टिक करें, यदि नहीं है तो 'नहीं'

पर टिक करें। कृपया टिक करें(✓) प्रत्येक आइटम के लिए सबसे उपयुक्त उत्तर। आपके द्वारा प्रदान की गई जानकारी गोपनीय रखी जाएगी और इसका उपयोग केवल शोध उद्देश्य के लिए किया जाएगा।

कथन	हाँ	नहीं
भौतिक कारक		
1. मेरे आस-पास कोई निदान/उपचार सुविधा नहीं थी।		
2. मैं अपने घर के काम/नौकरी में बहुत व्यस्त थी।		
3. स्तन की गांठ बहुत छोटी थी.		
4. लक्षण मेरे लिए कोई दर्द या परेशानी पैदा नहीं कर रहे थे।		
ज्ञान कारक		
5. मुझे नहीं पता था कि स्तन में देखे गए इन परिवर्तनों के लिए परामर्श के लिए कहाँ जाना चाहिए।		
6. मैंने सोचा कि यह गर्भावस्था/स्तनपान के प्रभाव के कारण है।		
7. मुझे ब्रेस्ट कैंसर के बारे में जानकारी नहीं थी.		
8. मैंने सोचा कि इससे अपने आप राहत मिल जायेगी.		
9. मैंने सोचा कि यह गंभीर नहीं है और इसके लिए चिकित्सकीय देखभाल की आवश्यकता नहीं है।		

कथन	हाँ	नहीं
मनोवैज्ञानिक कारक		
10. मुझे डर था कि दूसरे लोग इसके बारे में क्या सोचेंगे।		
11. मुझे अपनी स्थिति के बारे में दूसरों को बताने में शर्म आती थी।		
12. मैं COVID-19 महामारी के कारण बाहर जाने से डर रही थी।		
13. यह मैं स्वीकार नहीं करना चाहता थी।		
14. मुझे पति के छोड़ देने का डर था।,		
15. मैं कैंसर या किसी गंभीर बीमारी के संभावित निदान से डरती थी।		
16. मैं इलाज से डर गई थी।		
17. मुझे स्वास्थ्य देखभाल प्रणाली पर भरोसा नहीं था।		
18. मुझे डर था कि कहीं मैं मर न जाऊं।		
सामाजिक-सांस्कृतिक कारक		
19. मेरे धर्म ने मुझे इस स्थिति के बारे में चिकित्सीय परामर्श लेने की अनुमति नहीं दी।		
20. मैंने पहले इन लक्षणों के लिए वैकल्पिक उपचार की तलाश की।		
21. मैं इलाज के खर्च को लेकर चिंतित था।		
22. अन्य (निर्दिष्ट करे).....		

ANNEXURE 4

LIST OF EXPERTS FOR CONTENT VALIDITY

SR.NO	NAME OF EXPERT	DEPARTMENT & DESIGNATION
	NURSING COLLEGE, AIIMS BHOPAL	
1.	Dr. Anurag bhai Patidar	Medical surgical nursing Associate professor College of Nursing, AIIMS Bhopal
2.	Mrs. Ranjana Verma	Medical surgical nursing Assistant professor College of Nursing, AIIMS Bhopal
3.	Mr. R Velmurugan	Medical surgical nursing Assistant professor College of Nursing, AIIMS Bhopal
4.	Mr. Kumarasamy AP.	Medical surgical nursing Assistant professor College of Nursing , AIIMS Bhopal
	AIIMS BHOPAL	
5.	Dr. Sunil Kumar	Visiting consultant Medical Oncology AIIMS, Bhopal
6.	Dr. Vikaspal	Senior Resident Department of Radiotherapy AIIMS, Bhopal
	EXTERNAL VALIDATORS	
7.	Dr. Preksha Sharma	Oncology Nursing Associate Professor College of Nursing , Faridkot University
8.	Mr. Anil Kumar	Medical surgical Nursing Associate Professor College of Nursing , Faridkot University
9.	Mrs. Prabha Agnibhoj	Oncology Nursing Lecturer College of Nursing ,BMHRC, Bhopal
10.	Ms. Aditi Prasant Sinha	Associate professor Nursing college, AIIMS New Delhi
11.	Mrs. Sushma Chawla	Clinical instructor R.A.K. College of Nursing, New Delhi

ANNEXURE 5

LETTER REQUESTING EXPERTS' OPINION AND SUGGESTIONS FOR THE CONTENT VALIDITY OF TOOL

LETTER REQUESTING EXPERTS OPINION AND SUGGESTIONS FOR THE CONTENT VALIDITY OF RESEARCH TOOL

Date :

From,

Kajal Nehra

M.Sc. Nursing (Batch 2022-24)

Nursing college, AIIMS Bhopal.

To,

.....

.....

Subject : Requesting the expert's opinion and suggestion for the content validity of research tool

Respected Sir/ Madam,

I, Kajal Nehra, M.Sc. Nursing (Batch 2022-24) student in Oncology Nursing at Nursing College of AIIMS Bhopal. I have selected the topic mentioned below for my dissertation to be submitted as partial fulfillment of Masters in Nursing Degree programme, at the nursing college, AIIMS Bhopal.

Title of the study:"Delay in presentation to the hospital and factors affecting it among the BreastCancerpatients"

In this regard I have prepared the following:

1. Self Structured tool for data collection in English
2. Self Structured tool for data collection in Hindi

Kindly go through the tool and give your valuable remarks and suggestion for any modification needed in the content.
I shall be grateful to you for your valuable remarks and suggestion.

Thanking you.
Enclosed with
Brief synopsis, research tool, criteria checklist for content validity of the tool, certificate of validation.
Your sincerely,
Kajal Nehra
M.Sc. Nursing (Batch 2022-24)
GUIDE

Dr. Jisa George T.
Assistant Professor.
College of Nursing, AIIMS Bhopal

डॉ जिसा जॉर्ज टी/Dr.Jisa George T
सहायक प्राध्यापिका/Assistant Professor
नर्सिंग महाविद्यालय/Nursing College
एम्स भोपाल, मध्य प्रदेश-462020
AIIMS Bhopal, (M.P.)-462020

Co-Guide

Dr. Rajesh Pasricha
Professor and Head
Department of Radiotherapy

डॉ. राजेश पसरीचा/Dr.Rajesh Pasricha
प्राध्यापक और प्रमुख/Professor and Head
विभाग/Department of Radiotherapy (Radiation Oncology)/(Radiation Oncology)
(रेडियोथेरेपी विभाग)
अखिल भारतीय आयुर्विज्ञान संस्थान भोपाल-462020
All India Institute of Medical Sciences Bhopal-462020

Co-Guide.
Mrs. GeetaBhardwaj
Assistant Professor
College of Nursing, AIIMS Bhopal

नसीमा शफकत/ Naseema Shafqat
सहायक प्राध्यापिका/Assistant Professor
नर्सिंग महाविद्यालय/Nursing College
एम्स भोपाल, मध्य प्रदेश-462020
AIIMS Bhopal, (M.P.)-462020

Dr. MamtaVerma
I/C PRINCIPAL
Nursing College, AIIMS Bhopal

3/4/2023

ANNEXURE 6

CRITERIA CHECKLIST FOR THE VALIDATION OF THE TOOL

Dear Experts,

This study consists self- structured tool , which consists following:

- Section A- Socio-demographic and Clinical characteristics of patient with breast cancer patients.
- Section B – Contain self structured questionnaire to assess time lag since detection of mentioned breast cancer symptoms in the breast by women and presentation to hospital .
- Section C - Contain self structure questionnaire to assess factors affecting the presentation to the hospital among breast cancer patients.

Section A- Socio-demographic characteristics of patient with Breast cancer patients.

- It consists of four item under Socio-economic status scale of Kuppuswamy.
- 7 items under Socio- demographic data of the Breast Cancer patient.
- Four items under clinical data of Breast Cancer patient.
- We need your expertise judgement on degree of relevancy of each item to the measure domain. If there are any suggestions and modifications, please mention in the remark column.
- Your expert opinion and kind cooperation will be highly appreciated.

Item number	Highly relevant 4	Quite relevant 3	Somewhat relevant 2	Not relevant 1	Remarks
Socio demographic data of the breast cancer patient 1. 2. 3.					

4. 5. 6. 7.					
Clinical data of Breast Cancer patient 1. 2. 3. 4.					

Section B : Questionnaire to assess presentation delay

Item number	Highly relevant 4	Quite relevant 3	Somewhat relevant 2	Not relevant 1	Remarks
1.					
2.					

Section C : Questionnaire to a assess affecting delayed presentation

Item number	Highly relevant 4	Quite relevant 3	Somewhat relevant 2	Not relevant 1	Remarks
1.					
2.					
3.					
4.					
5.					
6.					
7.					

8.					
9.					
10.					
11.					
12. **13.**					
14.					
15.					
16.					
17.					
18.					
19.					
20.					
21.					
22.					

ANNEXURE 7

CONTENT VALIDATION CERTIFICATE

CERTIFICATION OF VALIDATION

This is to certify that Questionnaire/Tool constructed by Kajal Nehra, M.Sc. Nursing 2022-24 batch student, Nursing College, AIIMS Bhopal, to be used in her study titled - "**Delay in presentation to the hospital and factors affecting it among the Breast Cancer patients"** has been validated by me and is found to be valid.

Overall Remark :

Signature:

Name of the Expert:

Designation:

Name of the Institution:

Official Seal:

Date:

Place:

ANNEXURE 8

CERTIFICATE OF TRANSLATION (HINDI)

Hindi Validation Certificate

This is to certify that Kajal Nehra; M.Sc. Nursing student of Nursing College, AIIMS Bhopal conducting Research on the topic "**Delay in presentation to the hospital and factors affecting it among the Breast cancer patient**" .

This tools for data collection is translated from English language to Hindi language by me. The Hindi tool is valid to collect the data for Research.

डॉ. अर्पणा बादल

सहायक प्राध्यापक हिन्दी
सरोजनी नायडू शासकीय कन्या
स्नातकोत्तर (स्वशासी) महाविद्यालय
भोपाल (म.प्र.)

Seal & Signature

Name of the expert : डॉ० अर्पणा बादल

Qualification : पी-एच.डी.

Designation : सहायक प्राध्यापक; हिन्दी

Name of the institute: सरोजनी नायडू शासकीय कन्या स्नातकोत्तर (स्वशासी) महाविद्यालय, भोपाल (म०प्र०)

Date :

Place:

ANNEXURE 9

CERTIFICATE OF TRANSLATION (ENGLISH)

Validation Certificate

This is to certify that Kajal Nehra; M.Sc. Nursing student of Nursing College, AIIMS Bhopal conducting Research on the topic **"Delay in presentation to the hospital and factors affecting it among the Breast cancer patient"** .

This tools for data collection is translated from Hindi language to English language by me. The English tool is valid to collect the data for Research.

Thakur

.....

Seal & Signature

Name of the expert : Dr. Jyoti Thakur

Qualification : Phd

Designation : Guest Faculty

Name of the institute: Department of Comparative Languages and Culture

Date :

Place: Barkatullah University, Bhopal

Forwarded

(डॉ. अघेलाल)
विभागाध्यक्ष
तुलनात्मक भाषा एवं संस्कृति विभाग
बरकतउल्ला विश्वविद्यालय, भोपाल

ANNEXURE 10

LETTER SEEKING PERMISSION TO CONDUCT THE STUDY

DEAN (Nursing/Paramedics) Office AIIMS, BHOPAL (M.P.) 462020 Received No. 295 Date 1/7/23

NURSING COLLEGE, OFFICE AIIMS, BHOPAL (M.P)-462020 Dispatch No. 10254 Date: 28/06/23

NURSING COLLEGE, OFFICE AIIMS, BHOPAL (M.P)-462020 Received No. 11030 Date: 3/7/23

From,
Kajal Nehra
Masters of Science (Oncology Nursing) Student
(2022-2024 batch)
Nursing College ,AIIMS Bhopal

To,
The Medical Superintendent
AIIMS Bhopal

Receipt: 2905 MSO/AIIMSBPL Dated: 28.6.23.

DEAN (Nursing/Paramedics) Office AIIMS, BHOPAL (M.P.) 462020 Dispatch No. 941 Date: 3/7/23

Dispatch: 2905 MSO/AIIMSBPL Dated: 28/6/23

(Through proper channel)

Subject-Letter seeking permission for conducting Research study at AIIMS Bhopal.

Respected Sir,

As a part of the curriculum, myself Kajal Nehra ; Masters of Science (Oncology Nursing) student, AIIMS Bhopal conducting a Research study titled **"Delay in presentation to the hospital and factors affecting it among the breast cancer patients "**

The study is approved by the IHEC-SR of AIIMS Bhopal and LOP has been received for the same (Enclosed).

I seek your permission for the data collection for research study (Pilot study and main study) from Oncology department (Onco- Radiation Therapy ,Oncology Medicine and Onco-Surgery ward and OPD).

Kindly grant permission for the same. I shall be obliged to you.
Submitted for your kind perusal.

Thanking you.
Kajal Nehra Kajal 22/06/23
(Student Investigator)
(+91-7210866989)
Kajaln.mscnursing22@aiimsbhopal.edu.in

Dr. Jisa George 22/06/23
Assistant Professor
GUIDE

Mrs. Neela Bhardwaj 22/06/23
Assistant professor
CO-GUIDE

Dr. Rajesh Rastrela
Prof. and HOD of Radiotherapy
CO-GUIDE

Dr. Mamta Verma
Associate professor
I/C Principal
College of nursing
AIIMS Bhopal
26/6/2023

Permitted.
Shashank
28/6/23

Offg. Dean (N/P)

Cc:- Associate Dean + Dean N/P
Dr Jisa + Kanak
3/7/23
3/7/23
Principal (I/c)
For mandeep
03.07.23

ANNEXURE 11

PARTICIPANT INFORMATION SHEET (ENGLISH)

Participant Information Sheet

1. **STUDY TITLE: Delay in presentation to the hospital and factors affecting it among the breast cancer patients**
2. **STUDY INVESTIGATORS:**
3. **Student:** (Name, Department) : Kajal Nehra, M.Sc. Nursing (Oncology Nursing)
4. **Guide** (Name, Department): Dr. Jisa George T , Medical – Surgical Nursing
5. **Co- Guide/s** (Name, Department): Mrs. Geeta Bhardwaj , Obstetrics and Gynaecology Nursing
   Dr. Rajesh Pasricha ,Department of Radiotherapy
6. **Introduction**:

We are conducting a research study to reduce the increasing load of mortality due to breast cancer and their four we need to lay emphasis on early detection of breast cancer. Early detection itself depends on early presentation to the health facility. If you agree to take part voluntarily, we will ask you to sign a consent form.

7. **Purpose of the study:**
   The main name of the study is to assess the time lag since first detection of breast cancer symptoms and presentation to the hospital among breast cancer patients and the factors affecting delayed presentation to the hospital among breast cancer patients.
8. **Taking part – it involves:**

a. Do I have to take part?

Participation in this research is entirely voluntary. A decision to not take part, or to withdraw at any time, will not affect your rights or medical care in any way.

b. What is expected of me if I take part?

If you participate, you will have to fill some tools or answer questions by self or telephonically

c. How long will my part in the study last?

Your participation in the study would last for one time only.

d. Do I have to come for extra visits or undergo extra investigations for the study?

No additional visits is required for the study

e. What are the possible benefits in taking part?

The study will assess the delay in presentation and factors affecting delayed presentation among breast cancer patient which can be a baseline data for future interventions to prevent breast cancer delayed presentation to health care facility.

f. What are the possible disadvantages and risks of taking part?

There are no major foreseeable disadvantages or risks because of the study. There may be risk of loss of privacy and confidentiality of information collected even though all possible measures will be taken to ensure safe data storage and access.

g. What happens to the information collected from me?

All information collected will be kept strictly confidential and not shared with anyone. Results from the study will be reported as group data and will not identify you in any way.

h. What if I change my mind regarding participation in the study?

You are entitled to change your mind and withdraw at any time during the study without any disadvantage or penalty.

i. Whom do I contact for more information or if I have further questions or concerns?

If you want any information or have questions or concerns, you can contact:

Kajal Nehra.
Post graduate student,
M Sc . Oncology Nursing, AIIMS Bhopal
(7210866989).
(KAJALN.mscnursing22@aiimsbhopal.edu.in)

Dr. Shashank Purwar
Member Secretary,
Institute Ethics Committee – Student Research
(7773010099,ihecpgr@aiimsbhopal.edu.in)

ANNEXURE 12

PARTICIPANT INFORMATION SHEET (HINDI)

प्रतिभागी सूचना पत्र

9. **अध्ययन शीर्षक: अस्पताल में प्रस्तुति में देरी और स्तन कैंसर के रोगियों में इसे प्रभावित करने वाले कारक**

10. **अध्ययन अन्वेषक:**

11. **विद्यार्थी:**(नाम, विभाग) : काजल **नहरा**, एम.एससी। नर्सिंग (ऑन्कोलॉजी नर्सिंग)

12. **मार्गदर्शन देना**(नाम, विभाग): डॉ जीसा जॉर्ज टी, मेडिकल - सर्जिकल नर्सिंग

13. **सह-गाइड / एस**(नाम, विभाग): श्रीमती गीता भारद्वाज, प्रसूति एवं स्त्री रोग नर्सिंग

    डॉ. राजेश पसरीचा, रेडियोथेरेपी विभाग

14. **परिचय**:

हम स्तन कैंसर के कारण मृत्यु दर के बढ़ते भार को कम करने के लिए एक शोध अध्ययन कर रहे हैं इसलिए हमें स्तन कैंसर का जल्द पता लगाने पर जोर देने की जरूरत है। शुरुआती पहचान ही स्वास्थ्य सुविधा के लिए प्रारंभिक प्रस्तुति पर निर्भर करती है। यदि आप स्वेच्छा से भाग लेने के लिए सहमत हैं, तो हम आपसे एक सहमति फॉर्म पर हस्ताक्षर करने के लिए कहेंगे।

15. **इस अध्ययन का उद्देश्य:**

    अध्ययन का मुख्य नाम स्तन कैंसर के रोगियों में पहली बार स्तन कैंसर के लक्षणों का पता लगाने और अस्पताल में पेश करने के बाद से समय अंतराल का आकलन करना है और स्तन कैंसर रोगियों के बीच अस्पताल में देरी से प्रस्तुति को प्रभावित करने वाले कारक हैं।

16. **भाग लेना - इसमें शामिल है:**

a. **क्या मुझे भाग लेना है?**

इस शोध में भागीदारी पूरी तरह से स्वैच्छिक है। भाग न लेने या किसी भी समय वापस लेने का निर्णय किसी भी तरह से आपके अधिकारों या चिकित्सा देखभाल को प्रभावित नहीं करेगा।

b. **यदि मैं भाग लेता हूँ तो मुझसे क्या अपेक्षा की जाती है?**

यदि आप भाग लेते हैं, तो आपको कुछ टूल्स भरने होंगे या प्रश्नों का उत्तर स्वयं या टेलीफोन से देना होगा

c. **अध्ययन में मेरा हिस्सा कितने समय तक चलेगा?**

अध्ययन में आपकी भागीदारी केवल एक बार के लिए रहेगी।

d. **क्या मुझे अध्ययन के लिए अतिरिक्त मुलाकातों या अतिरिक्त जांचों के लिए आना होगा?**

अध्ययन के लिए किसी अतिरिक्त विज़िट की आवश्यकता नहीं है

e. **भाग लेने के संभावित लाभ क्या हैं?**

अध्ययन प्रस्तुति में देरी और स्तन कैंसर रोगी के बीच देरी से प्रस्तुति को प्रभावित करने वाले कारकों का आकलन करेगा जो स्वास्थ्य देखभाल सुविधा में स्तन कैंसर की देरी से प्रस्तुति को रोकने के लिए भविष्य के हस्तक्षेप के लिए आधारभूत डेटा हो सकता है।

f. भाग लेने के संभावित नुकसान और जोखिम क्या हैं?

अध्ययन की वजह से कोई बड़ा अनुमानित नुकसान या जोखिम नहीं हैं। एकत्र की गई जानकारी की गोपनीयता और गोपनीयता के नुकसान का जोखिम हो सकता है, भले ही सुरक्षित डेटा भंडारण और पहुंच सुनिश्चित करने के लिए सभी संभव उपाय किए जाएंगे।

g. मुझसे एकत्र की गई जानकारी का क्या होता है?

एकत्र की गई सभी सूचनाओं को कड़ाई से गोपनीय रखा जाएगा और किसी के साथ साझा नहीं किया जाएगा। अध्ययन के परिणाम समूह डेटा के रूप में रिपोर्ट किए जाएंगे और किसी भी तरह से आपकी पहचान नहीं करेंगे।

h. क्या होगा अगर मैं अध्ययन में भाग लेने के बारे में अपना विचार बदल दूं?

आप अपना विचार बदलने और अध्ययन के दौरान किसी भी समय बिना किसी नुकसान या दंड के वापस लेने के हकदार हैं।

i. अधिक जानकारी के लिए या मेरे और प्रश्न या चिंताएँ होने पर मैं किससे संपर्क करूँ?

यदि आप कोई जानकारी चाहते हैं या आपके कोई प्रश्न या चिंताएँ हैं, तो आप संपर्क कर सकते हैं:

काजल नेहरा.
स्नातकोत्तर विद्यार्थी,
एम एससी। ऑन्कोलॉजी नर्सिंग, एम्स, भोपाल
(7210866989)।
(KAJALN.mscnursing22@aiimsbhopal.edu.in)

डॉ. शशांक पुरवार
सदस्य सचिव,
संस्थान आचार समिति - छात्र अनुसंधान
(7773010099,ihecpgr@aiimsbhopal.edu.in)

ANNEXURE 13

INFORMED CONSENT SHEET

प्रतिभागी सूचना सहमति प्रपत्र

[PARTICIPANT INFORMED CONSENT FORM (PICF)]

इस अध्ययन के लिए प्रतिभागी का पहचान नंबरः .....

Participant Identification number for the study: .....

अनुसंधान का शीर्षक : अस्पताल में प्रस्तुति में देरी और प्रस्तुति में देरी के कारण स्तन मरीजों में।

Title of Project : Delay in presentation to the hospital and factors affecting it among the breast cancer patients.

शोधकर्ता छात्र का नाम : काजल नहरा फोन नं: 7210866989

Name of Student Investigator : Kajal Nehra Tel No.(s) : 7210866989

शोध मार्गदर्शक का नाम : डॉ. जिसा जॉर्ज टी

Name of Thesis Guide : Dr. Jisa George T

मैंने दिनांक 20.08.2022 के सूचना पत्रक संस्करण II में दिए गए सभी तथ्यों को सावधानीपूर्वक पढ़ लिया है/ मुझे अपनी भाषा में स्पष्ट रूप से विस्तारपूर्वक समझा दिया गया है, और मैंने तथ्यों को पूर्णतः समझ लिया है। मैं पुष्टि करता/ करती हूँ, कि मुझे सवाल पूछने के अवसर प्रदान किए गए। The contents of the information sheet version II dated 20 August 2022 that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

मुझे इस अध्ययन की प्रकृति एवं उद्देश्य और इसके संभावित जोखिमों / लाभों तथा अध्ययन की अनुमानित अवधि एवं अन्य प्रासंगिक जानकारी के बारे में विस्तारपूर्वक समझा दिया गया है। मुझे पता है कि इस अध्ययन में मेरी भागीदारी स्वैच्छिक है तथा मैं इस अध्ययन से किसी भी समय बिना कोई कारण बताए, अपना नाम वापस लेने के लिए स्वतंत्र हूं और नाम वापस लेने पर मेरी चिकित्सा देखभाल या कानूनी अधिकारों पर कोई प्रभाव नहीं पड़ेगा। The nature and purpose of the study and its potential risks/benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

मैं समझता/समझती हूं कि इस अनुसंधान में मेरी भागीदारी से मेरे बारे में एकत्र की गई जानकारी और मेरे चिकित्सीय दस्तावेजों के किसी भी भाग को एम्स के जिम्मेदार व्यक्तियों द्वारा ही देखा जाएगा। मैं इन व्यक्तियों को मेरे रिकॉर्ड प्राप्त करने की अनुमति प्रदान करता/ करती हूँ। I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from AIIMS. I give permission for this individuals to have access to my records.

यदि प्रतिभागी बच्चा है तो उसकी मौखिक या लिखित सहमति प्राप्त की गई है। If participants is child, his/her verbal of written assent has been obtained.

मैं उक्त अध्ययन में भाग लेने के लिए सहमत हूं/I agree to take part in the above study.

_____

(प्रतिभागी के हस्ताक्षर / बांए अंगूठे का निशान) (Signature/Left Thumb Impression)

दिनांक/Date……स्थान/Place …….....

प्रतिभागी का नाम/Name of the participant…….....

पिता/पति/पत्नी का नाम /Son/Daughter/Spouse of…….

डाक का पूरा पता /Complete Postal Address …….....

अगर अशिक्षित हों / If illiterate.

सूचना पत्र को प्रतिभागी को पढ़ा और समझाया गया है और प्रश्न पूछने का अवसर दिया गया है। मैं पुष्टि करता हूं कि व्यक्ति ने स्वतंत्र रूप से अपनी सहमति दी है।

The information sheet has been read and explained to the participant and given the opportunity to ask questions. I confirm that the individual has given consent freely.

कानूनी रूप से स्वीकार्य प्रतिनिधि या निष्पक्ष गवाह के हस्ताक्षर

Signature of Legally acceptable representative or impartial witness.

दिनांक/Date

एलएआर या निष्पक्ष गवाह का नाम / Name of LAR or impartial witness .

पता / Address :-

प्रमाणित किया जाता है कि उक्त सहमति मेरी उपस्थिति में प्राप्त की गई।

This is to certify that the above consent has been obtained in my presence.

_____

छात्र शोधकर्ता के हस्ताक्षर दिनांक…… स्थान……

Signature of the student Investigator Date …… Place ……

कृपया ध्यान दें: **सहमति प्रपत्र तीन प्रतियों में (1) रोगी के लिए, (2) शोधकर्ता, (3) संस्थान के लिए तैयार करें।**
(छात्रों से अनुरोध है कि आसानी से समझ आने योग्य हिंदी अनुवाद स्वयं तैयार करें)

NB: Three copies should me made, for (1) Patient, (2) Researcher, (3) Institution
(Students are requested to prepare the translation in simple understandable Hindi on their own.)

ANNEXURE 14

MASTER DATA SHEET

SOCIO-DEMOGRAPHIC DATA OF THE BREAST CANCER PATIENT

1. Age group (in years)

a. 18 – 28 **1**
b. 29 – 39 **2**
c. 40 – 50 **3**
d. 51 – 60 **4**

2. Level of education…….

a. Unable to read and write ( ) **0**

b. Primary education and less. ( ) **1**

c. Secondary education ( ) **2**

d. Higher secondary education ( ) **3**

e. College and above ( ) **4**

3. Occupation status……..

a. Housewife ( ) **0**

b. Government employee ( ) **1**

c. Private employee ( ) **2**

d. Have own business ( ) **3**

e. Other(specify) ( )…… **4**

4. Marital status……..

a. Unmarried ( ) **0**

b. Married ( ) **1**

c. Divorced ( ) **2**

d. Widowed ( ) **3**

5. Residence…….

a. Rural area ( ) **0**

b. Urban area ( ) **1**

6. If married, Number of children……

f. Nil ( ) **0**
g. 1 ( ) **1**
h. 2 ( ) **2**

i. 3 ( ) **3**
j. >3 ( ) **4**

7. Religion……..

a. Hindu ( ) **0**

b. Muslim ( ) **1**

c. Christian ( ) **2**

d. Other (specify) ( )…… **3**

8.. Is there any history of oral contraceptive pills use, if yes; what is the duration?

a. Yes **1**
b. No **0**

SOCIO- ECONOMIC STATUS SCALE OF KUPPUSWAMY

1. Education of the Head

Variable	Answer
h. Profession or Honours	
i. Graduate	
j. Intermediate or diploma	
k. High school	
l. Middle School	
m. Primary school	
n. Illiterate	

2. Occupation of Head of the family

Variable	Answer
h. Professionals	
i. Semi- professional	
j. Clerical/Shop/ Farmer	
k. Skilled workers	
l. Semi- Skilled workers	
m. Unskilled Worker	

n. Unemployed	

3. Total monthly income of the family

Variable	Answer
a. Equal to more than 185,895	
b. 92,951 – 185,894	
c. 69,535 – 92,950	
d. 46,475 – 69,534	
e. 27883 – 46474	
f. 9308 – 27882	
g. less than or equal to 9307	

Social Status based on Kuppuswamy Scale

Total Score	**Social Status**	**Coding**
26 – 29	Upper	**1**
16 – 25	Upper middle	**2**
11- 15	Lower middle	**3**
5 - 10	Upper lower	**4**
< 5	Lower	**5**

CLINICAL DATA

VARIABLES	**CATEGORY**	**CODE**
1) What is First change of breast is observed?	○ Breast Lump ○ Swelling under axilla / palpable axillary lymph nodes ○ Breast pain ○ Tingling ○ Nipple problems/ Abnormal Discharge per nipple ○ Two breast are not equal in size or shape	**0** **1** **2** **3** **4** **5** **6** **7**

	○ Breast dimpling ○ Other	
2) Do you have Family history of breast cancer?	○ Yes If yes, What is the relation?..... ○ No	**1** **0**
3) How frequently you perform Breast self examination?	○ At least once a month ○ Every 3 month ○ Rarely or never (Rarely = <2 times a year)	**0** **1** **2**
4) Do you have any Comorbid disease, if yes what is the time period of comorbid illness?	○ HTN, if yes, duration…… **0** ○ Diabetes, if yes, duration…… **1** ○ TB, if yes, duration…… **2** ○ Cardiac disease, if yes, duration…….. **3** ○ Other(specify)…… **4** ○ No comorbid illness **5**	**Yes = 1** **No = 0**

<u>SECTION B</u> : QUESTIONNAIRE TO ASSESS PRESENTATION DELAY

1. When did you first observe the above-mentioned symptoms about breast cancer?
   ……
2. What is the duration between the first time you noticed changes in your breasts and the first time you visited a medical health facility?

   ……(days/ week/month/year)

   a. 0.5 – 3 month **0**
   b. >3 – 12 month **1**
   c. >12 month **2**

<u>SECTION C</u> : QUESTIONNAIRE TO ASSESS FACTORS AFFECTING DELAYED PRESENTATION

Yes = 1

No = 0

STATEMENT	YES	NO
Physical Factor		
1) There was no diagnostic/ treatment facility near me.		
2) I was too busy in my household chores/ job.		
3) Breast Lump was too small.		
4) The symptoms were not causing any pain or discomfort for me.		
Knowledge Factor		
5) I didn't know where to go for consultation for these observed breast changes.		
6) I thought it is due to pregnancy/ effect of lactation.		
7) I didn't have knowledge about Breast Cancer.		
8) I thought it will relieved by itself.		
9) I thought it was not serious and didn't require medical attention.		
Psychological Factors		
10) I was afraid what others will think about it.		
11) I was embarrassed to talk about my breast condition to others.		
12) I was afraid to going out due to COVID-19 pandemic.		
13) It doesn't want to accept my condition/ Denial.		
14) I had fear of husband abandonment.		
15) I was afraid of possible diagnosis of Cancer or any severe illness.		
16) I was afraid of the treatment		
17) I didn't had trust on health care system.		
18) I had fear that I might die.		
Socio-Cultural Factors		

19) My religion didn't allow me to take medical consultation about this condition		
20) I sought alternative treatment first for these symptoms.		
21) I was concerned about the cost for the treatment.		
22) Any other (specify)…… .		

SOCIO-DEMOGRAPHIC VARIABLES DATA SHEET

CODE	1	2	3	4	5	6	7	8	SOCIAL STATUS
M1	4	0	0	1	1	2	0	0	3
M2	2	2	0	1	1	2	1	0	4
M3	4	2	0	1	1	2	0	0	4
M4	4	0	0	1	0	4	0	1	4
M5	3	2	0	1	0	4	0	0	4
M6	3	0	0	1	0	2	0	0	4
M7	4	4	1	1	0	2	0	0	3
M8	4	4	0	1	1	2	1	0	3
M9	3	2	1	1	0	2	0	0	3
M10	3	4	0	1	1	2	0	1	3
M11	3	4	2	1	1	2	3	0	2
M12	4	3	0	1	1	2	0	0	3
M13	2	4	0	1	1	2	0	0	1
M14	4	0	0	1	1	2	0	0	3
M15	2	1	0	1	1	3	0	0	4
M16	3	4	0	1	1	2	0	0	3
M17	3	1	4	1	0	4	0	0	4
M18	4	0	0	1	0	4	0	0	4
M19	4	0	0	1	0	3	0	0	4
M20	2	2	0	1	0	3	0	0	4
M21	2	2	0	1	0	2	0	0	3
M22	4	3	0	1	1	4	0	0	3
M23	4	3	0	1	1	2	0	0	2
M24	3	2	1	1	1	3	0	0	4
M25	4	0	4	1	0	4	0	0	5
M26	4	0	0	1	0	2	0	0	3
M27	4	4	1	3	1	2	0	0	3
M28	3	2	0	1	1	2	0	0	4
M29	3	4	2	1	1	2	0	1	3
M30	4	2	0	3	0	2	0	0	4
M31	3	1	0	1	0	1	0	0	4
M32	2	2	0	1	1	3	0	0	4
M33	3	2	0	1	0	2	0	0	4
M34	4	1	0	3	1	3	0	0	2
M35	2	0	0	1	0	3	0	0	4
M36	3	2	3	1	0	1	0	0	4
M37	4	3	0	1	1	2	0	0	4
M38	3	2	0	1	1	3	0	0	4
M39	3	4	3	0	1	0	0	0	3
M40	3	4	0	3	1	4	1	0	4
M41	3	3	0	1	0	3	0	1	3
M42	4	2	0	1	0	3	0	0	4
M43	3	4	1	1	1	2	0	0	2

M44	2	2	0	1	0	2	0	0	4
M45	4	1	0	1	1	2	0	0	4
M46	3	2	0	1	1	2	0	0	4
M47	2	4	2	1	1	1	0	0	3
M48	2	2	4	1	1	3	0	0	4
M49	4	1	0	1	0	3	0	0	4
M50	3	2	0	1	0	3	0	1	4
M51	2	0	0	1	0	3	0	0	4
M52	4	0	4	1	0	4	0	0	4
M53	3	1	0	1	0	4	0	0	4
M54	4	0	0	1	0	2	0	0	3
M55	3	2	0	1	1	2	0	0	3
M56	4	1	0	1	0	3	0	0	4
M57	1	2	0	1	0	3	0	0	4
M58	4	0	4	1	0	4	0	0	5
M59	3	2	0	1	1	1	1	0	3
M60	4	0	0	1	0	2	0	0	4
M61	3	1	4	1	1	2	0	0	3
M62	2	2	3	1	0	2	0	0	4
M63	3	4	1	1	1	3	0	0	2
M64	4	1	0	1	1	3	0	0	4
M65	2	0	0	1	1	2	0	0	4
M66	3	0	0	3	0	3	0	0	4
M67	2	2	0	1	0	2	0	0	4
M68	2	1	0	1	0	2	0	0	4
M69	3	1	0	1	0	2	0	0	4
M70	4	1	0	1	0	2	0	0	4
M71	3	0	0	1	0	2	0	0	4
M72	2	3	0	1	1	2	0	0	4
M73	3	0	0	1	1	3	1	0	4
M74	3	2	0	1	0	4	0	0	3
M75	4	2	0	1	0	4	0	0	4
M76	3	0	0	1	1	2	0	0	3
M77	2	2	3	1	0	2	0	0	4
M78	3	4	2	1	1	3	1	0	3
M79	3	0	0	1	1	2	0	0	4
M80	3	0	0	1	0	4	0	0	4
M81	4	0	0	3	0	4	0	0	4
M82	3	2	0	3	0	1	0	1	4
M83	4	1	0	1	1	3	1	0	3
M84	3	2	0	1	1	1	0	0	4
M85	3	1	0	1	1	3	0	0	4
M86	3	4	0	1	1	2	0	0	3
M87	2	0	0	1	0	2	0	0	3
M88	3	4	0	1	1	2	0	0	3
M89	4	0	0	1	1	3	0	0	4

M90	3	0	0	2	1	4	1	0	5
M91	4	2	0	1	1	1	0	0	2
M92	3	1	0	1	1	3	0	0	3
M93	4	3	0	1	1	4	0	0	1
M94	3	1	0	1	0	3	0	0	4
M95	3	0	0	3	1	3	0	0	4
M96	3	2	0	1	0	2	0	0	3
M97	3	1	0	1	0	2	0	0	4
M98	3	0	4	1	0	3	0	0	5
M99	2	4	0	1	0	2	0	0	4
M100	4	3	0	3	1	3	0	0	3
M101	4	2	0	1	1	3	0	0	2
M102	3	2	2	1	1	3	0	0	4
M103	2	3	0	1	1	2	0	0	4
M104	4	2	0	1	1	3	0	0	4
M105	2	4	0	1	0	0	1	0	2
M106	4	2	0	1	1	2	0	0	3
M107	3	2	0	3	0	4	0	0	4
M108	4	1	0	1	0	4	0	0	3
M109	3	0	0	1	0	4	0	0	3
M110	3	0	0	1	0	3	1	0	4
M111	4	0	0	1	1	3	0	0	4
M112	2	1	3	1	1	1	0	0	3
M113	4	1	0	1	0	2	0	0	4
M114	4	2	0	1	1	2	0	1	5
M115	4	0	0	1	0	2	0	0	5
M116	2	3	0	1	0	2	0	0	4
M117	3	0	4	1	0	3	0	0	4
M118	3	4	3	1	0	3	1	1	3
M119	4	1	0	1	0	3	0	0	4
M120	3	2	0	1	1	2	0	0	3
M121	2	4	0	1	1	2	0	0	3
M122	3	1	0	1	0	4	0	1	4
M123	3	0	0	1	0	4	0	0	4
M124	3	4	1	1	1	2	0	0	3
M125	4	4	0	1	1	2	0	0	3
M126	4	3	0	1	1	4	3	0	4
M127	3	4	3	1	1	2	3	0	3
M128	3	1	4	3	1	0	0	0	4
M129	1	4	4	0	0	0	0	0	4
M130	2	2	0	1	1	2	0	1	4
M131	4	1	0	1	1	4	1	0	4
M132	4	0	0	1	1	2	0	0	3
M133	2	2	0	1	1	2	1	0	4
M134	4	2	0	1	1	2	0	0	4
M135	4	0	0	1	0	4	0	1	4

M136	3	2	0	1	0	4	0	0	4
M137	3	0	0	1	0	2	0	0	4
M138	4	4	1	1	0	2	0	0	3

CLINICAL VARIABLES DATA SHEET

CODE	1	2	3	HTN	DM	TB	CD	OTHER	NO CO-MORBID
M1	3	0	2	0	1	0	0	0	0
M2	4	1	2	0	0	0	0	0	1
M3	0	0	2	1	0	0	0	0	0
M4	0	0	2	0	0	0	0	0	1
M5	6	0	2	0	0	0	0	0	1
M6	0	0	2	0	0	0	0	0	1
M7	0	0	2	0	0	0	0	0	1
M8	0	0	2	1	1	0	0	0	0
M9	0	0	2	0	0	0	0	1	0
M10	0	0	2	0	0	0	0	0	1
M11	3	0	2	0	0	0	0	0	1
M12	0	0	2	1	0	0	0	0	0
M13	0	0	2	0	0	0	0	0	1
M14	1	0	2	0	0	0	0	0	1
M15	0	0	2	0	0	0	0	0	1
M16	0	0	2	0	0	0	0	0	1
M17	0	0	2	0	0	0	0	0	1
M18	1	0	2	0	0	0	0	0	1
M19	0	0	2	0	0	0	0	0	1
M20	0	0	2	0	1	0	0	0	0
M21	0	0	2	0	0	0	0	0	1
M22	4	0	2	0	0	0	0	0	1
M23	0	0	2	0	0	0	0	0	1
M24	0	1	2	0	0	0	0	0	1
M25	0	0	2	0	0	0	0	0	1
M26	2	1	2	0	0	0	0	1	0
M27	0	0	2	0	1	0	0	0	0
M28	0	0	2	0	0	0	0	0	1
M29	0	0	2	0	0	0	0	0	1
M30	4	0	2	1	0	0	0	1	0
M31	0	0	2	0	0	0	0	0	1
M32	1	0	2	0	0	0	0	0	1
M33	0	0	2	0	0	0	0	0	1
M34	0	0	2	1	1	0	0	0	0
M35	0	0	2	0	0	0	0	0	1
M36	0	0	2	0	0	0	0	0	1
M37	0	0	2	0	1	0	0	1	0
M38	0	0	2	0	0	0	0	0	1
M39	2	0	2	0	0	0	0	1	0
M40	0	0	2	0	0	0	0	0	1
M41	5	0	2	0	0	0	0	1	0
M42	0	0	2	0	1	0	0	0	0
M43	2	0	2	0	0	0	0	0	1

M44	0	0	2	0	0	0	0	0	1
M45	0	0	2	0	0	0	1	0	0
M46	2	0	2	0	0	0	0	1	0
M47	4	0	0	0	0	0	0	0	1
M48	0	0	2	0	0	0	0	0	1
M49	0	0	2	1	0	0	0	0	0
M50	0	0	2	0	0	0	0	0	1
M51	0	0	2	0	0	0	0	0	1
M52	0	0	2	0	0	0	0	0	1
M53	0	0	2	0	0	0	0	0	1
M54	0	0	2	0	0	0	0	0	1
M55	0	0	2	0	0	0	0	0	1
M56	0	0	2	0	0	0	0	0	1
M57	0	0	2	0	0	0	0	0	1
M58	2	0	2	0	0	0	0	0	1
M59	4	0	2	1	0	0	0	0	0
M60	0	0	2	0	0	0	0	0	1
M61	0	0	2	1	0	0	0	0	0
M62	0	0	2	0	0	0	0	0	1
M63	2	0	2	0	0	0	0	0	1
M64	0	0	2	0	0	0	0	0	1
M65	0	0	2	0	0	0	0	0	1
M66	0	0	2	0	0	0	0	0	1
M67	0	0	2	0	0	0	0	0	1
M68	0	0	2	0	0	0	0	0	1
M69	0	0	2	0	0	0	0	0	1
M70	0	0	2	0	0	0	0	0	1
M71	0	0	2	0	0	0	0	0	1
M72	0	0	2	0	0	0	0	0	1
M73	0	0	2	0	0	0	0	0	1
M74	0	0	2	0	0	0	0	0	1
M75	0	0	2	0	0	0	0	0	1
M76	1	0	2	0	0	0	0	0	1
M77	0	0	2	0	0	0	0	0	1
M78	0	0	2	0	0	0	0	0	1
M79	0	0	2	0	0	0	0	0	1
M80	0	0	2	0	0	0	0	0	1
M81	0	0	2	0	0	0	0	0	1
M82	0	0	2	0	0	0	0	0	1
M83	0	0	0	0	0	0	0	0	1
M84	0	0	2	0	0	0	0	0	1
M85	0	0	2	0	0	0	0	0	1
M86	4	0	2	0	0	0	0	0	1
M87	2	0	2	0	0	0	0	0	1
M88	0	0	2	0	0	0	0	1	0
M89	0	0	2	0	0	0	0	1	0

M90	0	0	2	0	0	0	0	0	1
M91	0	0	2	0	0	0	0	0	1
M92	0	0	2	0	0	0	0	0	1
M93	0	0	2	0	0	0	0	0	1
M94	0	1	2	0	0	0	0	0	1
M95	0	0	2	0	0	0	0	0	1
M96	0	0	2	0	1	0	0	0	0
M97	0	0	2	0	0	0	0	0	1
M98	0	0	2	1	0	0	0	0	0
M99	0	0	2	0	0	0	0	0	1
M100	2	0	2	0	0	0	0	0	1
M101	0	1	0	1	0	0	0	0	0
M102	0	0	2	1	0	0	0	0	0
M103	0	0	2	0	0	0	0	0	1
M104	2	0	2	0	0	0	0	0	1
M105	0	0	2	0	0	0	0	0	1
M106	1	0	2	1	0	0	0	0	0
M107	0	0	2	0	0	0	0	1	0
M108	0	1	2	0	0	0	0	0	1
M109	0	0	2	0	0	0	0	0	1
M110	0	0	2	0	0	0	0	0	1
M111	0	0	2	1	1	0	0	0	0
M112	5	0	2	0	0	0	0	0	1
M113	0	0	2	0	0	0	0	0	1
M114	0	0	2	0	0	0	0	0	1
M115	0	0	2	1	0	0	0	1	0
M116	0	0	2	0	0	0	0	0	1
M117	1	0	2	0	0	0	0	0	1
M118	0	0	2	0	0	0	0	0	1
M119	0	0	2	0	0	0	0	0	1
M120	0	0	2	1	0	0	0	0	0
M121	0	0	2	0	0	0	0	0	1
M122	0	0	2	0	0	0	0	0	1
M123	0	0	2	0	0	1	0	0	0
M124	0	1	2	0	0	0	0	0	1
M125	0	0	2	1	0	0	0	0	0
M126	4	1	2	1	1	0	0	0	0
M127	3	0	2	0	1	0	0	0	0
M128	0	0	2	0	0	0	0	0	1
M129	2	0	2	0	0	0	0	0	1
M130	0	0	2	0	0	0	0	0	1
M131	0	0	2	0	0	0	0	0	1
M132	3	0	2	0	1	0	0	0	0
M133	4	1	2	0	0	0	0	0	1
M134	0	0	2	1	0	0	0	0	0
M135	0	0	2	0	0	0	0	0	1

M136	6	0	2	0	0	0	0	0	1
M137	0	0	2	0	0	0	0	0	1
M138	0	0	2	0	0	0	0	0	1

DELAY IN PRESENTATION DATA SHEET

CODE	duration (coding)	duration in month
M1	0	2
M2	0	0.59
M3	0	0.65
M4	0	2.5
M5	0	1
M6	0	3
M7	1	4.3
M8	0	1.5
M9	0	2
M10	0	2
M11	0	0.65
M12	1	12
M13	0	0.91
M14	0	2
M15	0	1
M16	0	0.72
M17	0	1
M18	0	1
M19	1	6
M20	0	3
M21	0	2.16
M22	1	6
M23	2	132
M24	0	0.82
M25	2	36
M26	0	1.06
M27	0	3
M28	0	0.65
M29	1	12
M30	1	5
M31	1	5
M32	0	2
M33	0	3
M34	0	0.65
M35	1	8
M36	1	12
M37	0	0.78
M38	0	0.5
M39	0	1
M40	1	12
M41	0	1
M42	1	3.32
M43	0	1.75
M44	0	3

M45	1	5
M46	0	1
M47	0	2
M48	0	2
M49	0	1
M50	1	9
M51	1	12
M52	0	1
M53	1	7
M54	0	2
M55	1	3.39
M56	1	6
M57	0	2
M58	0	3
M59	1	5
M60	1	11
M61	1	7
M62	0	2
M63	1	5
M64	1	9.06
M65	1	5
M66	0	1
M67	0	3
M68	2	24
M69	1	10
M70	2	36
M71	0	1
M72	0	1
M73	0	1
M74	0	2.49
M75	2	24
M76	0	0.72
M77	0	2
M78	0	2
M79	1	9
M80	0	2
M81	0	1
M82	0	2.36
M83	0	0.65
M84	0	1
M85	0	3
M86	0	1
M87	0	1
M88	0	1
M89	2	24
M90	0	0.49

M91	0	1.13
M92	1	5
M93	0	3
M94	1	5
M95	0	2
M96	0	1
M97	1	5
M98	0	0.49
M99	0	2
M100	0	2
M101	0	0.62
M102	0	0.59
M103	1	6
M104	1	7
M105	2	168
M106	0	2.91
M107	1	6
M108	0	3
M109	0	1
M110	0	1
M111	0	2
M112	0	1
M113	0	2
M114	1	5
M115	0	0.65
M116	1	9
M117	0	1
M118	0	2
M119	0	0.65
M120	0	2
M121	1	6
M122	0	1
M123	1	12
M124	2	299
M125	0	2
M126	2	71
M127	0	0.52
M128	1	12
M129	0	1
M130	1	6
M131	0	1
M132	0	2
M133	0	0.59
M134	0	0.65
M135	0	2.5
M136	0	1

M137	0	3
M138	1	4.3

FACTORS AFFECTING DELAYED PRESENTATION DATA SHEET

CODE	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12	S13	S14	S15	S16	S17	S18	S19	S20	S21	S22
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M2	1	1	0	1	0	0	1	1	1	1	1	0	1	0	1	1	0	0	0	1	1	1
M3	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
M4	0	0	0	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	1	1	0
M5	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M6	1	1	0	1	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	1	0	1
M7	0	0	1	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
M8	0	0	1	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
M9	1	0	0	1	0	0	1	1	1	1	0	0	0	0	1	1	0	0	0	0	0	0
M10	0	0	0	1	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
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M12	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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M14	0	0	1	1	1	0	0	1	1	1	0	1	0	0	0	0	1	0	0	0	0	0
M15	0	0	1	1	0	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
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M24	0	0	1	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
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M26	0	0	0	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
M27	0	0	1	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
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M29	0	1	1	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
M30	1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1
M31	0	0	0	1	0	0	1	1	1	0	0	0	1	0	0	0	0	0	0	0	0	0
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M126	0	1	0	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	1	0
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M134	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
M135	0	0	0	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	1	1	0
M136	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M137	1	1	0	1	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	1	0	1

M138	0	0	1	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0